Volume XXXVIII, Number 2 Fall 2007

The Journal of Research Administration

Published by

SRA International

Society of Research Administrators International

Celebrating 40 years of Excellence

Cover Photo:
This edition of the Journal of Research Administration is published as SRA International continues to celebrate its 40th anniversary. In this edition, the Journal celebrates the industry, craft and technology of the profession of research administration and its allied disciplines. Like the master woodworker carving instruments that will pluck at the raw center of human existence, the international service of research administrators is a masterful craft that makes possible the ways in which research touches the very core of what it means to be human.

The cover photo is used with permission from Fotosearch.

Editorial Staff

Editor
Edward F. Gabriele, MDiv, DMin

Senior Associate Editor
Bruce Steinert, PhD, CCRA

Associate Editors:
Timothy Atkinson, EdD
Frances Chandler, MA, PhD (cand)
Bruce Elliott, PhD
Lynda Hardy, PhD
Cindy Kiel, JD
David Langley, PhD
Phillip E. Myers, PhD
Mildred Ofosu, PhD
Pam Vargas, MBA

Manuscript Editors Board

Chair:
Mary Adams, MTS

Members:
Paula Bistak, RN, MS, CIP
Douglas Carroll, MRE, MLIS
Marie Cooper, IHM, EdD
Nathalie Coté, PhD
John Gillon, JD, MPH
Darlene Gilson
Anita Hartmann, PhD, CIP, CRA
Frances Jeffries, PhD
Elsa Nadler, EdD
Michael Owen, PhD
Debra Schaller-Demers, MSOM
Jackie Solberg, CRA
Marianne Ward, CRA

Journal Review Board

Chair:
Joseph Cosico, MA, CCRC, CRA

Members:
Rosemary Biscardi, MBA, CCRP
Gary Chadwick, PharmD, MPH, CIP
Jeffrey Cohen, PhD, CIP
Philip Cola, MA
Sandra Crocker, MBA
Erica Ellington, CRA
Marianne Elliott, MS, CIP
Carol Fedor, ND, RN, CCRC
John Gillon, JD, MPH
Stephanie Hafner, MA
Jim Hanlon, CHRP
Karen Hansen
Rene Hearns, MPA, CRA
Daniel Herr, MS, MD, FCCM
Elizabeth Holmes, PhD
Martin Jamieson, MBA, ACMA
Greg Koski, PhD, MD, CPI
Barbara LoDico, CIP
Michael McCallister, PhD
Jessica Moise
Sharon McCarl, MBA, CRA
Sandra Nordahl, CRA
Jennifer Morgan Shambrook, MHA
J. Michael Slocum, JD
Timothy Sparklin, MSW, CIM
Daniel Vasgird, PhD, CIP
Paul Waugaman, MPA

"Voice of Experience" Authors
Elliott Kulakowski, PhD
2007 Coordinator and Senior Writer
Lynne Chronister, MPA
Victoria Molfese, PhD
J. Michael Slocum, JD
Cliff Studman, PhD
Paul Waugaman, MPA

Publishing Coordinator
Valerie J. Ducker

Journal Correspondence

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

Subscriptions

Subscriptions: $100 per year in the United States, Canada, and Mexico; $125 per year international.

Make checks payable to *The Journal of Research Administration*.

Subscriptions for SRA Members are included as part of an individual's annual dues. All subscriptions are for two yearly editions. Send change-of-address notices (together with your address label) and all other correspondence regarding subscriptions and purchase of back issues to Society of Research Administrators International, Executive Office, 1901 North Moore Street, Suite 1004, Arlington, VA 22209 USA. Phone: +1-703-741-0140. Periodicals are postage paid at Arlington, VA and at an additional mailing office.

Copyright © 2007 by the Society of Research Administrators International (SRA).

All material subject to this copyright may be photocopied for limited non-commercial educational purposes with the written permission of the SRA and with appropriate credit. Opinions expressed in this Journal represent the opinions of the authors and do not reflect official policy of either the SRA or the author's affiliated institution unless so noted in the author's note portion of the specific article. Papers prepared by employees of the U.S. government as part of their official duties may not be copyrighted, but the Journal format is copyrighted and requires written permission of the Society of Research Administrators International, as outlined above. Copying for general distribution, resale, or other purposes may be authorized only with specific written permission from the Society of Research Administrators International. Requests for such permission must be made in writing to the Society of Research Administrators International, 1901 North Moore Street, Suite 1004, Arlington, Virginia 22209 USA or through Email at info@srainternational.org.

Officers Of The Society Of Research Administrators International

President	Philip Spina
President - Elect	Pamela Miller
Past President	Dorothy Yates
Treasurer	Frank Davis
Secretary	J. Terence Manns

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

Volume XXXVIII, Number 2

1. From the Editor's Desk 5
Edward Gabriele, DMin

2. Contributors 7

3. Articles

Research Administration as a Living System 14
Sharon Stewart Cole, PhD

Institutional Challenges of Interdisciplinary Research Centers 28
Sherry Glied, PhD, Suzanne Bakken, DNSc, Allan Formicola, DDS, Cristine Gebbie, DrPH, Elaine L Larson, PhD

Why Academics Have a Hard Time Writing Good Grant Proposals 37
Robert Porter, PhD

Internal Grant Competitions: A New Opportunity for Research Officers to Build Institutional Funding Portfolios 44
Rengarajan V. Balaji, MS, MBA, CRA, Christine Knisely, MA, Jack Blazyk, PhD

Application of Standard Project Management Tools to Research – A Case Study from a Multi-national Clinical Trial. 51
Peter Gist, PhD, David Langley, PhD

Customer-Supplier Roles and Relationships in the Management of Research Projects 59
Ian M. Carter, PhD

Implementing Ethics Policies in Developing Countries: Ploughing On Parched Ground? 67
Professor Isaac N. Mazonde, José Jackson-Malete, PhD, Jeremy Sugarman, MD, MPH, MA

Administration of an Innovative Program of International Cooperation: Success Across the Pond 78
Vincent S. Gallicchio, PhD, Dp (hon)

Book Review:
Managing Scientists: Leadership Strategies in Scientific Research (2004) Alice Sapienza, Wiley-Liss, Inc., 246 pp.. 86
Frances Chandler, MA, PhD (cand)

Law Review:
Recent Developments in Research Law 90
J. Michael Slocum, JD
Eric Guttag, JD
J. Mark Waxman, JD
Jill Williamson, JD

Voice of Experience
International Research Infrastructure and The Impact of
Export Control Regulations 107
Elliott C. Kulakowski, PhD
Lynne Chronister, MPA
Victoria Molfese, PhD
Michael Slocum, JD
Cliff Studman, PhD
Paul Waugaman, MPA

From the Editor's Desk

Many times the most ordinary things present us with the most extraordinary moments. That truth came home to me dynamically a short time ago. I was watching a woodworker install hardwood floors in a home being remodeled. Part of the project was the rebuilding of the main stairway. With sleeves rolled up for a long and steady stairway task, he singled out each piece of solid oak and carefully reviewed every line. Seasoned and calloused hands gently but definitely explored each inch of wood as if getting to know it personally. As he sawed and carved, it seemed nothing could distract him. Carefully and with undoubted knowledge, he cut each piece with exquisite precision. He sanded over and over again, and then stained each step with a red-gold mastery as if burning the color into each piece. He cured each step and carefully fit each precisely into place. As wood is one of my favorite media, I could not pull myself away but found myself drawn more and more into the mastery that was taking place. As he began to put the finishing touches on his work, I caught a glimpse of something that arrested my attention. There, while he was staining, sanding and curing, I saw a single bead of perspiration catch on the end of an eyelash. I thought I saw a flash, a glint. It seemed that for one brief second I was caught up in a fire that I never expected. Something enduring swept open a path. Labor and passion met mastery and brilliance. For one brief moment, it seemed I had left my own time and space and had journeyed back centuries to witness a lost form of expression. I was watching a master. This was no mere technician. This was no assembly line production. This was more than just the remodeling of a set of stairs. This was art. Here was what the ancient Greeks would call *"techne."* Craft. And suddenly my definition of "technology" had changed – in the swift glint of a bead of sweat washing an eyelash of inspiration.

Dr. Edward Gabriele

This edition of the Journal of Research Administration occurs as we draw to a close the 40th anniversary of the Society of Research Administrators International. It strikes me as important that this edition of the Journal celebrates the craft, the technology and the industry that is our profession. Our profession is the sometimes awkward conjoining of inspiration and perspiration. We sense the technology that is ours sometimes with that same bead of sweat that prisms the glint behind our eyes when we have brought a tedious contract to fruition, or completed a critical proposal review, or finalized a patent application. Regardless of the specific task, our profession is itself a hard hewn art that requires the masterful care of building, and fitting, and staining, and curing. It is a process. Sometimes it splinters. But if fired with red-gold dedication, it is a fitting stairway that facilitates the traffic of human ideas and processes and invention. Indeed, ours is a craft that captures both industry and innovation.

In this edition, our craft, our industry, our technology, and our innovation are celebrated in special and unique ways. Dr. Sharon Stewart-Cole invites us to consider research administration as a systemic reality while Dr. Elaine Larson and colleagues complete professional analysis on interdisciplinarity in research first considered in the previous edition. Dr. Robert Porter, and Mr. Remgarajan Balaji and his colleagues explore various means of bringing the service of research administrators most effectively to investigators and research communities. After these considerations, various international authors present us with provocative and important considerations concerning how our technologies serve researchers in diverse nations and cultures.

Dr. Peter Gist and Dr. David Langley explore how programs of service can be enriched by project management methods and technologies. Noting the current debate in research ethics concerning customer-service terminology, Dr. Ian Carter discusses how these same concepts can be reinterpreted to highlight research administration as a service with important levels of accountability to those who depend upon our efforts. In another vein, Dr. Isaac Mazonde and his colleagues reflect critically upon the challenges of research ethics in international cultures. To complete our global reflections upon the craft and technology of research administration, Dr. Vincent Gallicchio reminds us that our profession must truly be stretched — never tied to one place or one time — but ordered to the common good that makes us truly international. Our considerations are rounded out by two insightful book and law reviews from Ms. Frances Chandler and Mr. J. Michael Slocum. The volume is then completed by another highly informative edition of Voice of Experience as prepared by Dr. Elliott Kulakowski and the VOE Co-Authors.

The articles in this edition of the Journal are a point of unique pride for each of us in research administration leadership. In 1916, Carl Sandburg published his famous "Chicago Poems." Many of us are very familiar with the central selection of that work. Seeming to burst with Middle American pride, Sandburg boasts Chicago as…..

"Hog Butcher for the World,
Tool Maker, Stacker of Wheat,
Player with Railroads and the Nation's Freight Handler;
Stormy, husky, brawling,
City of the Big Shoulders….."

Sandburg uses the city of Chicago as a type of personification of the human spirit that rejoices in the buzz and hum of labor and industry and invention. He celebrates the "doing" that is not just American, but that belongs to every culture, in every time, and in every place.

We indeed are a "Profession of the Big Shoulders." We bear up much. And we know why. We know the stakes. Despite the challenges we may encounter and the set-backs that we may know occasionally, we celebrate the inspiration and the perspiration that we expend on behalf of those we serve. Perhaps this is the image, the glint, of the art-form and the industry that we call research administration. As we celebrate an anniversary, we look to the next generation that will continue to help build human progress through research of every discipline. Perhaps the greatest gift we can give to those who will come after us is a wonderfully raucous spirit bursting with pride-of-industry. Perhaps our celebration this year is best capped by echoing Sandburg's words:

"Under the terrible burden of destiny laughing as a young man laughs,
Laughing even as an ignorant fighter laughs who has never lost a battle,
Bragging and laughing that under his wrist is the pulse.
and under his ribs the heart of the people,
Laughing!
Laughing the stormy, husky, brawling laughter of Youth,
half-naked, sweating, proud to be
Hog Butcher, Tool Maker, Stacker of Wheat,
Player with Railroads and Freight Handler to the Nation."

Rengarajan V. Balaji is a Research Grants Development Coordinator at the Office of Research and Grants at the Ohio University College of Osteopathic Medicine. Mr. Balaji has Masters degrees in Biological Sciences (focus on Neuroscience) and Business Administration. More recently, he also obtained the CRA (Certified Research Administrator®) certification. Mr. Balaji has over six years of experience in various fields pertaining to research and research administration. Over the last four years, he has focused more on grant writing and preparation of research grant proposals. Mr. Balaji has seven peer-reviewed publications (including the current one) in scholarly journals and four research abstracts at scientific conferences. He is well-versed with the grant administration processes (Pre-Award) at NIH and NSF. He is an active member of NCURA and is part of their Pre-Award Neighborhood committee. His other honors include, reviewing responsibilities for three scholarly journals and a listing in Marquis Who's Who (2008, USA).

Dr. Jack Blazyk is Professor of Biochemistry in the Department of Biomedical Sciences and Associate Dean for Research and Grants in the Office of Research and Grants at the Ohio University College of Osteopathic Medicine. He received an A.B. degree in Chemistry from Hamilton College and a Ph.D. in Biochemistry from Brown University. Blazyk's laboratory has developed a novel design for antimicrobial peptides that may be effective against antibiotic-resistant bacteria. This work has been supported for the past eight years by the National Institutes of Health.

Dr. Ian Carter's career has spanned the capital engineering industry, an interdisciplinary research centre, and university administration and management. He is currently the Director of Research at the University of Liverpool, where he is responsible for the research portfolio, including the University's research strategy and policy development, oversight of all externally-funded research and knowledge transfer as Head of Research and Business Services. He is currently playing a leading role in the introduction of full economic costing, and is also involved in the RAE processes. He sits on the UK Research Councils' Joint Grants Processing Steering Group (under which he chairs the Research Organisation Consultation Group), and has been a member of various other Research Councils' Boards. He is a member of the national Costing and Pricing Group, and Technical Advisory Sub-Group. He is the Chair of the Association of Research Managers and Administrators (UK), is a leading member of the Brunswick Group, and is a member of the International Committee of the Society of Research Administrators International. His degrees are in Electrical and Electronic Engineering, and Engineering Design & Management Systems. He is a Chartered Engineer, and a member of the Institution of Electrical Engineers and the Chartered Management Institute.He has authored more than 130 peer-reviewed journal articles, 45 book chapters and 6 books. To date he has supervised 55 Masters and 23 Doctoral students. Among his many honors and awards, Gallicchio was recognized as the "Number One Rated Scientist in Clinical Laboratory Science" in the U.S. by Clinical Laboratory Science. He was elected as a Fellow of the Royal Society for the Encouragement of Arts,

Manufactures & Commerce and presented to Queen Elizabeth II of England at Buckingham Palace in 2004. Currently he serves as President of Alpha Eta, the national honor society devoted to academic scholarship in the Allied Health Professions and is President-elect of the International Federation of Biomedical Laboratory Science (IFBLS).

Frances Chandler is currently the Associate Director of Research Services at Brock University in Southern Ontario where she has worked for six years. Prior to her employment at the university she was engaged in research, teaching, social work and community development activities in China, Ghana, and Northern and Southern Ontario. She has a Bachelor of Environmental Studies Degree in Urban and Regional Planning, a Bachelor of Education degree and a Master of Arts in Social Welfare Policy. Currently Frances is a part time PhD student in education with a focus on leadership.

Dr. Sharon Stewart Cole is Contracts and Grants Administrator with the Nevada Cancer Institute in Las Vegas, Nevada. Prior to joining the Nevada Cancer Institute, she was Director in the Office of Sponsored Programs and Adjunct Professor in the Department of Education at Oklahoma City University. She received her doctorate from Capella University, College of Education, in Philosophy, Professional Studies in Education. She has also conducted workshops at the Oklahoma State Regents for Higher Education, Summer Grant Writing Institute, and served as a mentor to faculty to assist them in producing a final grant proposal.

Dr. Vincent Gallicchio is Associate Vice President of Research, Director of the Office of Sponsored Programs, and Professor of Biological Sciences and Public Health Science at Clemson University. He earned his B.A. in Biology and M.S. in Vertebrate Physiology from Southern Connecticut State University, M.T. from Yale University/ Hospital of St. Raphael School of Medical Technology, Ph.D. with distinction in Experimental Hematology from New York University, Post Doctoral Appointments at the University of Connecticut Health Center and Memorial Sloan-Kettering Cancer Center, and an honorary diploma in Physiology and Medicine from Vasile Goldis University in Arad, Romania. Gallicchio's research in AIDS and cancer has produced seven U.S. and one foreign patents and has been supported by grants from NIH, HRSA, VA, NATO, U.S. Department of Education, European Union and various pharmaceutical companies. He has authored more than 130 peer-reviewed journal articles, 45 book chapters and 6 books. Among his many honors, Gallicchio was recognized as the "Number One Rated Scientist in Clinical Laboratory Science" in the U.S. by Clinical Laboratory Science. He was elected a Fellow of the Royal Society for the Encouragement of Arts, Manufactures & Commerce and presented to Queen Elizabeth II of England at Buckingham Palace in 2004.

Dr. Peter Gist is Director, Ove Arup & Partners Ltd.
Dr Gist has been a consultant economist since 1975, specialising in the application of economics to business issues. He was a member of the economics faculty of London Business School from 1981 to 1989 and an advisor to the UK Departments of Industry and Transport on liberalisation and privatisation during the 1980's. He was involved in the privatisation of British Telecom including establishing the first regulatory "price cap" in the UK. Dr. Gist joined the privatisation services department of Price Waterhouse London in 1989 and managed a series of assignments on privatisation and restructuring in sectors including energy, telecommunications and transport for government and corporate clients in the UK, Europe and South East Asia. He was a founding Director of the economics consultancy BMP International in 1991 and joined Arup on its merger with BMP in 1999. He is now a Director in the Arup Transactions Advice team, conducting commercial and technical due diligence on mergers and acquisitions and providing business planning and strategic advice to Arup clients. He works extensively in the education and health sectors as well as in infrastructure intensive industries, and recently implemented an activity based costing system for research projects for Imperial College London.

Eric Guttag is a partner in the Cincinnati, Ohio office of the intellectual property law firm of Jagtiani + Guttag. He has over 30 years of corporate and private intellectual property law experience on various aspects of patent, trademark, copyright, trade secret and unfair competition matters. He has written or co-written over 30 articles on a wide variety of intellectual property law subjects including patents, trademarks, trade dress, copyright, computer law, Y2K issues, and Internet law, as well as conducted many presentations, including "Does the Research in Motion (BlackBerry) Case Apply to You? The Extraterritorial Enforcement of Patents" presented at the 2006 SRA International Annual Meeting. He is registered to practice before the United States Patent and Trademark Office, the Court of Appeals for the Federal Circuit, the Southern District of Ohio and the Court of Appeals for the 6th Circuit. He is a member of the American Intellectual Property Law Association, the Cincinnati Intellectual Property Law Association and the Cincinnati Bar Association. He has a B.A. degree (Magna Cum Laude, Phi Beta Kappa) in chemistry from Carleton College, and a J.D. degree from T. C. Williams School of Law, University of Richmond.

Dr. José Jackson-Malete is the Deputy Director of Research in the Office of Research and Development at the University of Botswana (UB). She assists the Director in the strategic management of research and directly oversees the funding and quality aspects of research administration. She has conducted research in the areas of responsible conduct of research and evaluating the research environment at UB. Jose is a food scientist with Masters and PhD degrees from Cornell University and Michigan State University, respectively. In addition to her research management duties, she also continues to do research in her field in the area of the quality

and safety evaluation of under-utilized indigenous fruits and vegetables, as well as diet, nutrition and its relationship to health outcomes such as obesity and HIV/ AIDS. Previously, she was Director of Research at the National Food Technology Research Centre in Botswana and Lecturer of Food Science at the University of the West Indies in Jamaica.

Christine B. Knisely is the Executive Director of the Office of Research and Grants at Ohio University College of Osteopathic Medicine. She has worked at the College for over ten years in the areas of grants and research administration and curriculum. Previous experience with grants includes work in the Ohio University College of Education. Prior to Ohio University, Ms. Knisely was the Assistant Director of the Ohio Humanities Council, a state-based agency of the National Endowment for the Humanities. Other grants-related experience includes work with non-profit civic and arts organizations. In 2005 she served on the National Conference Planning Committee for the Integrated Advanced Management Information Systems.

Dr. David Langley is Director of Research and Enterprise Development at the University of Bristol in the UK, which is internationally distinguished for teaching and research. He leads a professional team with varied roles including research strategy and policy, research and business development, relationship management, project management, contracting, research governance, ethics and misconduct and the full range of enterprise activities. He is a Board member of the Association of Research Managers and Administrators UK (ARMA) and on the Editorial Board for the UK for Research Global, published by the Association of Commonwealth Universities. Prior to his move to Bristol, he was Director of Research Services at Imperial College London (responsible for the management of a research grant portfolio of 5000+ awards) and before that a senior manager with the Medical Research Council, UK. Dr. Langley has worked in the private sector (project management and finance in engineering), the National Health Service (in clinical oncology research) and was a Fulbright Scholar where he undertook postdoctoral at the NIH. He has a PhD in neuropharmacology and is a Director and Trustee of The British School of Osteopathy. He is an Associate Editor of the Journal of Research Administration.

Dr. Elaine Larson is currently the Associate Dean for Research and Professor of Pharmaceutical and Therapeutic Research, Columbia University School of Nursing and Professor of Epidemiology, Columbia University Mailman School of Public Health. From 1992-8, she was Dean, Georgetown University School of Nursing, and Associate Director of Nursing, Georgetown Hospital. Dr. Larson is currently a member of the Board of Directors, National Foundation for Infectious Diseases and the Report Review Committee, National Academy of Sciences. She is the Director of an NIH-funded center, Center for Interdisciplinary Research in Antimicrobial Resistance. Dr. Larson has been Editor of the American Journal of Infection Control since 1994 and has published more than 200 journal

articles, four books and a number of book chapters in the areas of infection prevention, epidemiology, and clinical research.

Professor Isaac Mazonde is Director of Office of Research and Development at the University of Botswana. Professor Mazonde obtained his PhD from the University of Manchester (UK) in 1987. Between 1978 and 2000, he worked for the National Institute of Development Research and Documentation (NIR) within the University of Botswana, where he served as Research Fellow, Senior Research Fellow, Associate Professor and Acting Director. In June 2000 he was appointed Deputy Director of the Office of Research and Development of the University of Botswana, when the NIR was phased out. In 2005, he was appointed Director of the Office of Research and Development, the position he currently holds. Prof Mazonde's research interests include science and technology, social organization for economic production, and more recently, research management. He has published in all these areas. He has had study tours to research management organizations in the United States, South Africa and the United Kingdom. Todate, Prof Mazonde has attended three SRA Annual General Meetings and this is his second article to be published by the SRA Journal. From 2001 to 2007, he was a member of the Southern African Research and Innovation Management Association (SARIMA), which is affiliated to the SRA.

Dr. Robert Porter is Director of the Proposal Development Team in the Research Division at Virginia Tech. He has more than thirty years' experience as a tenured professor, private consultant and research administrator, and his proposals have won more than $5 million in awards from government agencies and private foundations. In addition to conducting workshops at universities and medical schools nationally, he has presented award-winning papers at major conferences and has published articles in the Journal of Research Administration. Dr. Porter has previously taught at Swarthmore College, Lewis and Clark College, and Susquehanna University. He holds graduate degrees in Speech Communications from the University of Michigan.

J. Michael Slocum is a senior member of the law firm of Slocum & Boddie, P.C. He has more than thirty years of experience in grant and contract law. He is a Distinguished Faculty member of the Society of Research Administrators, and has won the Excellence Award (2003) and the Hartford/Nicholson Award (1992) from that organization. Mr. Slocum is an honor graduate of DePauw University, and received his J.D. with honors from George Washington University National Law Center. He is a member of the Virginia State Bar, and is President of Slocum & Boddie, PC in Springfield, VA.

Dr. Jeremy Sugarman is the Harvey M. Meyerhoff Professor of Bioethics and Medicine, Professor of Medicine, Professor of Health Policy and Management, and Deputy Director for Medicine of the Berman Institute of Bioethics at the Johns Hopkins University. Dr. Sugarman conducts both theoretical and empirical research in medical ethics. His work concentrates on informed consent, research ethics, and the ethical issues associated

with emerging technologies. He is the author of approximately 150 publications in peer-reviewed journals, in addition to multiple reviews and book chapters as well as editing or co-editing four books. Dr. Sugarman serves on the Scientific and Research Advisory Board for the Canadian Blood Service and the Maryland Stem Cell Research Commission. He is currently Chair for the Ethics Working Group of the HIV Prevention Trials Network, the Ethics Officer for the Resuscitation Outcomes Consortium, and Co-Chair of the Johns Hopkins Embryonic Stem Cell Oversight Committee. Dr Sugarman is a member of the American Society of Clinical Investigation and a Fellow of the American Association for the Advancement of Science, the American College of Physicians, and the Hastings Center.

J. Mark Waxman is a partner with Foley & Lardner LLP, where he chairs the Health Care Industry Team and is a member of the White Collar Defense & Corporate Compliance Practice. Mr. Waxman's focus on health care for providers and payers includes issues related to research and technology, integrated delivery systems, governance, strategic business counseling, the antitrust implications of mergers and acquisitions, federal program fraud and abuse, reimbursement and managed care contracting. Mr. Waxman writes and lectures extensively on various issues including medical research and technology, compliance, managed care, antitrust issues, and health care fraud and abuse. He is a graduate of Boalt Hall School of Law, University of California, Berkeley (J.D., 1973), where he was Articles and Book Review Editor of the Ecology Law Quarterly, and the University of California, San Diego (B.A., summa cum laude, 1970). He was admitted to the California Bar in 1973, and the Massachusetts Bar in 2001 and is admitted to practice before the United States District Court, Central, Southern, Eastern and Northern Districts of California, the United States Court of Appeals, Eighth and Ninth Circuits, the United States Claims Court and the United States Supreme Court.

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 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). Dr. Kulakowski serves as the 2007 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.

Dr. Elliott Kulakowski

Lynne Chronister

Dr. Victoria Molfese

J. Michael Slocum

Dr. Cliff Studman

Paul Waugaman

Research Administration as a Living System

Sharon Stewart Cole, Ph.D.
Nevada Cancer Institute
One Breakthrough Way
Las Vegas, NV 89135
Work: 702-822-5119
Home: 702-855-0396
Fax: 702-944-2379
E-mail: scole@nvcancer.org

Author's Note

Portions of the literature review were previously reported with the author's dissertation research entitled, "Federal funding success factors: A replicated quantitative analysis." The author received her Ph.D. in Education in December 2006. The Delphi study in this article is new research that was performed to expand the findings of the author's dissertation research. The author has 20 years of experience in contracts and grants administration and has served as a director of sponsored programs.

Abstract

The purpose of this Delphi study was to gather expert opinions and recommendations for change in the research administration system to bring about growth and collaboration. This study was deemed important because at the heart of every system is the fact that individuals need each other to continue to exist. The results of the Delphi study give recommendations from the research faculty perspective for the improvement in the system of research administration and faculty relationships. Administrators and research faculty should view each other as team members whose objectives are to discover and understand how to achieve common goals. The recommendations suggested that change was needed by both faculty and research administrators to become a more unified, living system.

Keywords: Research administration, culture, grants, Delphi study, universities, research faculty, organization, principal investigator

Introduction

Imagine a university where faculty and research administrators work in harmony. Rather than strife, manipulation, placing blame, stress, and disallowances, a system where research administrators are empathic and helpful and receive accolades and recognition from faculty. Picture a system where faculty are supportive of research administrators and share their objectives and needs openly. Can you envision a university where faculty and research administrators receive and accept constructive feedback? Systems where university business practices support the research endeavor? Funding agencies support new research ideas and new researchers? How could such a system be accomplished? Previous research explains how these circumstances evolved, and is addressed in the literature review.

Literature Review

Publish or Perish Syndrome

Faculty are faced with the need to publish journal articles and books, and to obtain grant funding. This publish or perish syndrome is caused by universities using published research results to evaluate faculty for tenure, merit, funding, and salary decisions (Hu & Gill, 2000). Hu and Gill (2000) developed the theory of faculty

productivity as a life-cycle model, which states, "an individual engages in research because of the perceived significant future financial reward for the research activity" (p. 16).

This theory suggests that productivity rises sharply in the first stages of a career, peaks at the time of tenure, and then begins to decline. Hu and Gill (2000) found that the post-peak decline rate was slower for those in the high publication rate group compared to those in the low publication rate group. This finding followed the hypothesis that research provides reputation capital, which yields positive returns in subsequent years. Hu and Gill reported that faculty who took administrative positions such as department head or dean showed a significant drop in research productivity compared to their academic colleagues, and that productivity varied among institutions.

Hu and Gill (2000) noted that institutions could help by providing graduate assistants and reducing teaching and administrative duties. Taking this previous research into consideration, Hu and Gill attempted to "identify the set of variables that have the most significant effect on the research productivity of information systems faculty" (p. 24). Results of their data analysis lead to the following conclusions:

1. Junior faculty may be productive because of current technological skills, a strong reason that leads to longer working hours, more time allocated for research activities, and a light service load.

2. Senior faculty may be productive because of favorable teaching loads, opportunities to work with several junior faculty and doctoral students, or more time for research activities because of fewer new classes requiring preparation.

3. Faculty were adversely affected when assigned with a weekly teaching load of more than 11 hours, [by taking] on many academic service responsibilities, or [having] been in the faculty position for several years.

4. Tenure status, academic rank, and school type seemed to have no significant correlation to faculty research productivity. (p. 24)

The authors remarked that the life-cycle model has potential limitations that might influence reliability because the data are self-reported, and the numbers may be inflated for various reasons (Hu & Gill, 2000). What is clear is that the ability to participate in grant-funded research can be critical to new faculty seeking tenure and to institutions seeking funding to support research activities. Participating in research projects, preparing proposals, and publishing research results are traditionally considered activities of scholarship.

McMillin (2004) reported that becoming a complete scholar was a process through which junior faculty attempt to construct a professional identity:

[A senior faculty is] characterized as [having] a thirty-five year career, [being] an award-winning teacher, an effective dean, and a well-respected historian. He has managed to constantly reinvent himself and adapt to changes in theory and methodology, in pedagogy, student expectations, in institutional mission, and resource availability—all with grace, wit and modesty. (p. 1)

In contrast, junior faculty are characterized as being the lucky few survivors of a competitive job market, and technology has shaped their work both in teaching and research. They are beginning their careers at a time when the expectations of higher education are growing and societal

support for higher education institutions is declining. Many junior faculty are struggling to develop a professional identity, and new courses, and many are stretched to participate in community organizations. McMillin (2004) reported that participation in municipal projects, social service agencies, and schools is often part of the institutional mission. Many institutions protect junior faculty from this service mission and allow them to focus on traditional research.

McMillin believed that if new faculty do not find ways to make their research accessible to students, serve the local community, and build interdisciplinary connections before tenure, they most likely will not do so afterward. McMillin noted that the challenge was to find the right balance for new faculty so they could achieve a supportive flexible work environment in which to cultivate their academic professionalism.

The Competitive Nature of Federal Funding

Stigler (1993) reported that universities differ from businesses and athletics, which promote competition as a positive. On the other hand, a university, which views competition as a threat, "fosters complaints, cries for support, pleads for exemption from laws against collusion, and attempts to restrict new entries" (p. 1). Competition does take place among research universities and faculty. The competition focuses on the need to increase the intellectual gains to students and for faculty to derive economic gain from new ideas that advance science and human well being (Stigler). Faculty compete for higher salaries, larger offices, and recognition. Universities compete for prestige, students, and income; competition determines who is successful.

Stigler (1993) proposed that the difficulty faced by research universities was not in the competition between faculty and universities, but in the concentration of government support to a few major universities. In support of this position, Stigler discussed changes that have occurred with the National Science Foundation (NSF). He reported that around 1980, the NSF came under political pressure that impaired its efficiency and threatened injury to research universities. One of these dangers, he said, was the congressional earmarking of funds for state projects and the political setting of research agendas.

The NSF has considerable power in setting the direction of research and does not have a serious competitor in the physical and mathematical sciences. This agency, Stigler said, has turned its focus on "cultivating the source of the funds, the Congress, and has sought to structure its programs to increase its appeal to this source" (p. 7). Stigler explained how this change contributed to increased competition among research universities:

The National Science Foundation has found it easier to explain large-scale projects and research centers to Congress than to argue convincingly for the diffuse benefits of a broad-based funding of individual research grants; as a consequence the NSF has promoted large projects. The scientists have to a degree acquiesced in this shift, being told that otherwise it would be impossible to increase support to meet expanded challenges, and that the support for research centers in fact permits at least a modest growth of funding for other programs. But, that has not happened; instead, as might have been predicted, total budgets have not grown in real terms, and since the highly visible research centers have been enthusiastically sold to Congress, the centers have of necessity been spared the worst of the cuts. (p. 7)

Stigler (1993) offered words of encouragement for the research university, saying that, although universities face serious problems, they have already proven to be resilient and have emerged from these trials "changed and no less strong" (p. 9).

University Perspective

Boyer and Cockriel (1998) stated, "Research universities [were] judged by others based on research productivity and the dollar amount of acquired grants" (p. 61). Being "scholarly" was traditionally defined as "engaging in research, writing articles for publication, and sharing research findings with students" (p. 61). Writing proposals and being successful in receiving federal funding helped scholarly development and increased the opportunity for publication and recognition.

Ikenberry and Hartle (2000) showed that universities experienced a financial crisis as local government support for higher education fell sharply in the 1990s. With an economy pulling out of a recession, great pressure was placed on university budgets. Kennedy (1993) stated that universities were facing a period of serious resource constraint, and that without an infusion of new resources, the future of basic research might resemble the biomedical sciences.

> Applications for grants [were] growing faster than the available resources, the success ratio [was] declining, unrealistic demands for university matching [were] accompanied [by] reduced grant support, good research [was] going un-funded, good researchers [were] becoming frustrated, young researchers [were] leaving the field, infrastructure problems [were] being deferred, and the price for it all [was] paid by people who are not around to assert their interest. (pp. 2-3)

Universities and the federal government share interest in research that supports the continuation of sufficient grant funding. It is the mission of the university to serve the needs of society, and the government needs research to solve societal problems or concerns of national security. Society benefits from university research, the university research infrastructure is improved, new technologies are created, and the government agencies missions are supported (Federal Government and Higher Education, 1960).

Faculty Perspectives

To better understand the faculty's perspectives, Boyer and Cockriel (1998) studied motivational factors and barriers associated with pursuing federal funding:

> Motivators:
> 1. Consideration for tenure or promotion.
> 2. Building professional reputation as a capable researcher or Principal Investigator.
> 3. Strong commitment to federal funding from the college president.
>
> Barriers:
> 1. Lack of training in grant seeking and grant writing.
> 2. Lack of knowledge of budget development.
> 3. Lack of knowledge of funding sources. (1998, p. 61)

Boyer and Cockriel showed that the key to pursuing grant funding lies in discovering the individual motivators that attract faculty. This helps to reduce the barriers in the most cost-effective manner and stimulates the faculty's best work. McMillin (2004) stressed that institutions can create spaces where junior faculty can nurture their professional goals. Many institutions make "investments in faculty research by providing funding for start-up costs, research grants, travel support, sabbaticals, and pre-tenure leaves [of absence]" (p. 2). Research

universities' reputation seemed to follow research productivity, and such support was fair and needed (McMillin). This investment was supported by a "strong commitment and obligation of higher education to put the best minds of our society to work on creating new knowledge and its application to solve societal ills" (p. 2).

Porter (2004) reported that some new faculty acknowledged their need for career advancement and a specialization. This group recognized their need for training and scholarly development. Porter observed that there seem to be few mentors available to help new faculty in becoming successful. He further suggested that a series of training workshops with senior faculty serving as mentors would increase knowledge and skill and improve the attitudes of new faculty. Success in receiving federal funding would enhance the likelihood of achieving tenure, promotion, and academic freedom (Porter).

Research Administrator Perspective

In the 1960s, the federal government started many new programs that exploited the talents of faculty and the infrastructure of American universities. Federal agencies were established to manage these new initiatives through congressional budget allocations. Each agency independently established federal mandates and designed its own processes for managing its programs without coordination with other agencies (Management Concepts Incorporated, 1995):

> Dozens of different rules and procedures about how to deal with similar issues appeared. Each grants office devised its own standards, procedures, and forms for applying for federal funding. These [federal] institutions devised their own systems for determining how decisions would be made in awarding funding. (pp. 1-2)

This great diversity created by the federal agencies caused problems for universities. Policies, procedures, and federal regulations were extremely frustrating and confusing to applicants. It was necessary not only to determine the proper rules to follow, but also to understand the sometimes unspoken criteria for selection and management of awards (Management Concepts Incorporated, 1995). Federal Government and Higher Education (1960) noted:

> Grants [were] made because of proposals from individuals and groups, supported by their institutions. The size of the grant [was] determined through estimated direct costs of time, materials, and services, frequently supplemented by funds to pay for needed special equipment. A percentage fixed by law or regulation, of direct costs [was] applied toward the institution's indirect costs such as building maintenance and repair, utilities, and other items of general administrative expense. (p.81)

This system has grown so extensively that universities have given research administrators the responsibility to carry out the required proposal submission and grants administration operations in an efficient manner. The administration process is integral to the scholarly processes. The focus of research administration has been on observing the laws, rules and regulations imposed by funding agencies. This focus has in many institutions been perceived as a barrier to faculty, who in many cases feel these requirements have been communicated in ways that are less than helpful. Research administrators are frustrated by faculty's seeming lack of interest in or concern with their financial and compliance responsibilities.

Need for Change

Christopher and Gordon (1999) noted that systems form through collaboration and from a realization that we need one

another to maintain life. The recognition that individuals need each other lies at the heart of every system. From that realization individuals reach out, and seemingly divergent self-interests develop into a system of interdependency (Christopher and Gordon).

Those of us have worked in universities for many years know that we do not succeed nearly as often as we need to. We have suffered from the unending changes that overtake our universities, creating more destruction than growth (Christopher and Gordon, 1999). So, what hope is left? Is there a way to create change in the large, complex systems we have created? The answer is yes — when something is impossible through one vision, it possible through another, as Christopher and Gordon note:

> In a complex system it is possible to find simple causes that explain our problems, or to know whom to blame. A messy tangle of relationships has given rise to those unending crises. We need a different worldview to guide us in this new world of continuous change and intimately connected systems that reach around the globe…All living systems are webs of relationships spun into existence as individuals realize that there is more benefit available to them if they create relationships than if they stay locked in narrow boundaries of self-interest. These relationships of mutual benefit lead to creating systems that are more supportive and protective of individuals. It's important to remember that nothing living lives alone. Life always and only organizes as systems of interdependency. (p. 2)

When a system falls apart, it can see things differently and regenerate itself into a new way of living. Research administration as a living system can reform itself as it recognizes its weaknesses and cultivates shared interests with research faculty.

Study Methodology

Because there is so little systematic information about the working relationship between research administrators and faculty, a Delphi study was undertaken to gauge the opinions of faculty at several major research universities. Research faculty are the generators of the grants administration workload and recipient of services; therefore, their opinions and participation are deemed important to the improvements of the system of research administration. This Delphi study was not designed to determine statistical significance, to involve busy experts in an approach similar to a focus group. Unlike a focus group, the Delphi participants did not meet physically. An online survey was prepared by the researcher and distributed through email to individual participants. The researcher served as a clearinghouse through which the survey responses of each panelist were seen (Department of Sustainability and Environment, 2007).

The panelists were senior faculty at major research universities that have received at least $1 million in federal funding. A letter was distributed to 287 possible panelists to confirm their willingness to participate. The letter contained a description of the project, its objectives, the time anticipated, and a promise of anonymity. Of 34 senior faculty researchers who agreed to participate, 32 completed the two-step process. The four open-ended questions posed are listed below:

> Question 1: What support or services should research administrators give faculty that are not offered?
>
> Question 2: What should be the future goals and objectives of research administration?

Question 3: What change is needed in research administrators' attitudes toward working with faculty, and how should the change be implemented?

Question 4: What change is needed in faculty attitudes toward working with research administrators, and how should the change be implemented?

During the first round, the survey questions generated 134 opinions. Similar opinions were offered by many participants and were later synthesized to delete duplicates and to combine themes into 40 distinct opinions or recommendations for change. Based on the 40 opinions, a second and final survey was generated to assess the importance of each opinion regarding growth or change needed in research administration. The 32 faculty experts who participated in the final round of surveys rated the significance the 40 opinions or recommendations on a five-level scale. Level 1 was given the highest priority rating and Level 5 was given the lowest. The percent of faculty response to each of the 40 questions was calculated.

Results

The opinions were specific to how faculty perceived their interaction with their respective research administration offices and what they believed research administration should do to improve services offered. A majority of the Delphi panel agreed on several recommendations for change. Overall Level 1 responses to the 40 questions in the final survey averaged 45% of the total. The responses are shown in Table 1 below:

Table 1

Summary of Recommendations by Level of Significance (N=32)

Question 1: What support or services should research administrators give to faculty that are not offered?

1. Assist with preparing proposals, prepare budgets and proposal forms, streamline procedures for timely proposal review; and provide mentoring and proposal critiquing as needed.

	Response Percent	Response Count		Response Percent	Response Count
Level 1	46.9%	15	Level 4	6.2%	2
Level 2	21.9%	7	Level 5	0.0%	0
Level 3	25.0%	8			

2. Write the proposals if the university wants funding.

	Response Percent	Response Count		Response Percent	Response Count
Level 1	9.4%	3	Level 4	21.9%	7
Level 2	3.1%	1	Level 5	65.6%	21
Level 3	0.0%	0			

3. Change in services is not required. Faculty are being provided with all the help by Research Administrators that they need.

	Response Percent	Response Count		Response Percent	Response Count
Level 1	6.2%	2	Level 4	18.8%	6
Level 2	15.6%	5	Level 5	34.4%	11
Level 3	25.0%	8			

4. Help more and become less of an enforcer.

	Response Percent	Response Count		Response Percent	Response Count
Level 1	58.1%	18	Level 4	0.0%	0
Level 2	19.4%	6	Level 5	6.4%	2
Level 3	16.1%	5	N/A		1

5. Develop better graduate student recruiting strategies.

	Response Percent	Response Count		Response Percent	Response Count
Level 1	21.9%	7	Level 4	9.4%	3
Level 2	37.5%	12	Level 5	12.4%	4
Level 3	18.8%	6			

6. Reduce bottlenecks for better financial accounting, and reporting of grant funds, and timelier purchasing.

	Response Percent	Response Count		Response Percent	Response Count
Level 1	34.4%	11	Level 4	6.2%	2
Level 2	34.4%	11	Level 5	3.1%	1
Level 3	21.9%	7			

7. Communicate the university research objectives to granting agencies.

	Response Percent	Response Count		Response Percent	Response Count
Level 1	15.6%	5	Level 4	25.0%	8
Level 2	9.4%	3	Level 5	18.8%	6
Level 3	31.2%	10			

8. Work closely with faculty to plan a long-term university-wide research strategy.

	Response Percent	Response Count		Response Percent	Response Count
Level 1	21.9%	7	Level 4	12.5%	4
Level 2	25.0%	8	Level 5	6.2%	2
Level 3	34.4%	11			

9. Encourage faculty to pursue research funding by offering awards, prizes, grant writing workshops; and recognition for outstanding research.

	Response Percent	Response Count		Response Percent	Response Count
Level 1	12.5%	4	Level 4	12.5%	4
Level 2	34.4%	11	Level 5	12.5%	4
Level 3	28.1%	9			

10. Follow-up with notifications to faculty of progress reporting and renewal proposals deadlines.

	Response Percent	Response Count		Response Percent	Response Count
Level 1	25.0%	8	Level 4	12.5%	4
Level 2	43.7%	14	Level 5	9.4%	3
Level 3	9.4%	3			

11. Return a significant part of the overhead or indirect cost to the college, department, and principal investigator.

	Response Percent	Response Count		Response Percent	Response Count
Level 1	67.8%	21	Level 4	0.0%	0
Level 2	25.8%	8	Level 5	3.2%	1
Level 3	3.2%	1	N/A		1

12. Add more research administration staff during times of peak proposal deadlines to overcome frustration and alleviate the increased workload.

	Response Percent	Response Count		Response Percent	Response Count
Level 1	31.3%	10	Level 4	6.2%	2
Level 2	46.9%	15	Level 5	6.2%	2
Level 3	9.4%	3			

13. Facilitate institutional financial support (matching) for large scale-grant applications.

	Response Percent	Response Count		Response Percent	Response Count
Level 1	50.0%	16	Level 4	0.0%	0
Level 2	37.5%	12	Level 5	3.1%	1
Level 3	9.4%	3			

Question 2: What should be the future goals and objectives of research administration?

1. Identify proper funding agencies and programs beyond distribution of lists of announcements and web site links.

	Response Percent	Response Count		Response Percent	Response Count
Level 1	34.4%	11	Level 4	12.5%	4
Level 2	28.1%	9	Level 5	3.1%	1
Level 3	21.9%	7			

2. Help develop inter-disciplinary or research clusters to facilitate large-scale university proposals.

	Response Percent	Response Count		Response Percent	Response Count
Level 1	25.0%	8	Level 4	15.6%	5
Level 2	40.6%	13	Level 5	0.0%	0
Level 3	18.8%	6			

3. Encourage talented faculty members to achieve their full potential as researchers by standing behind faculty who are pursuing basic research.

	Response Percent	Response Count		Response Percent	Response Count
Level 1	46.9%	15	Level 4	6.2%	2
Level 2	31.3%	10	Level 5	9.4%	3
Level 3	6.2%	2			

4. Visit researchers' laboratories and open lines of effective communication by appreciating issues that the other person encounters.

	Response Percent	Response Count		Response Percent	Response Count
Level 1	9.4%	3	Level 4	18.8%	6
Level 2	28.0%	9	Level 5	18.8%	6
Level 3	25.0%	8			

5. Reduce the time researchers spend with administrative and paper work duties.

	Response Percent	Response Count		Response Percent	Response Count
Level 1	68.8%	22	Level 4	0.0%	0
Level 2	25.0%	8	Level 5	3.1%	1
Level 3	3.1%	1			

Question 3: What change is needed in research administrators' attitudes toward working with faculty and how should the change be implemented?

1. Recognize common goals and essential service functions of research administration to help the faculty member succeed.

	Response Percent	Response Count		Response Percent	Response Count
Level 1	31.3%	10	Level 4	3.1%	1
Level 2	31.3%	10	Level 5	0.0%	0
Level 3	34.3%	11			

2. Reduce arbitrarily implemented policies and be less rigid in their attitudes. Be more open to views of faculty.

	Response Percent	Response Count		Response Percent	Response Count
Level 1	38.7%	12	Level 4	6.4%	2
Level 2	35.5%	11	Level 5	0.0%	0
Level 3	19.4%	6	N/A		1

3. Try to understand the research before imposing restrictions on faculty's ability to make program or budget decisions.

	Response Percent	Response Count		Response Percent	Response Count
Level 1	16.1%	5	Level 4	12.9%	4
Level 2	32.3%	10	Level 5	0.0%	0
Level 3	38.7%	12	N/A		1

4. Offer service as the greater purpose and not just attending to compliance.

	Response Percent	Response Count		Response Percent	Response Count
Level 1	53.1%	17	Level 4	6.3%	2
Level 2	25.0%	8	Level 5	0.0%	0
Level 3	15.6%	5			

Question 4: What change is needed in faculty attitudes toward working with research administrators and how should the change be implemented?

1. Educate administrators of publication and grantsmanship relationship and requirements.

	Response Percent	Response Count		Response Percent	Response Count
Level 1	21.9%	7	Level 4	12.5%	4
Level 2	28.1%	9	Level 5	0.0%	0
Level 3	37.5%	12			

2. Send proposals with enough lead-time for the research administration office's review and submission and not route at the last minute.

	Response Percent	Response Count		Response Percent	Response Count
Level 1	28.1%	9	Level 4	12.5%	4
Level 2	28.1%	9	Level 5	6.3%	2
Level 3	25.0%	8			

3. Understand that administrators are trying to facilitate grant submission and administration and to treat administrators with mutual respect.

	Response Percent	Response Count		Response Percent	Response Count
Level 1	21.9%	7	Level 4	3.1%	1
Level 2	43.8%	14	Level 5	3.1%	1
Level 3	28.1%	9			

4. Interact with research administrators to bring their research to the attention of funding agencies and the public and in finding industrial connections.

	Response Percent	Response Count		Response Percent	Response Count
Level 1	22.6%	7	Level 4	3.2%	1
Level 2	32.3%	10	Level 5	6.5%	2
Level 3	35.4%	11	N/A		1

5. Work as a team and show each other respect.

	Response Percent	Response Count		Response Percent	Response Count
Level 1	46.9%	15	Level 4	3.1%	1
Level 2	28.1%	9	Level 5	3.1%	1
Level 3	18.8%	6			

6. Be more sensitive to the time of research administration personnel and their workload.

	Response Percent	Response Count		Response Percent	Response Count
Level 1	12.9%	4	Level 4	6.5%	2
Level 2	38.7%	12	Level 5	3.2%	1
Level 3	38.7%	12	N/A		1

7. Take a non-aggressive, open-minded approach toward research administrators.

	Response Percent	Response Count		Response Percent	Response Count
Level 1	34.4%	11	Level 4	6.3%	2
Level 2	37.4%	12	Level 5	3.1%	1
Level 3	18.8%	6			

8. Learn to trust research administrators, appreciate their role in securing funding, see them as partners, and delegate.

	Response Percent	Response Count		Response Percent	Response Count
Level 1	25.8%	8	Level 4	3.2%	1
Level 2	48.4%	15	Level 5	9.7%	3
Level 3	12.9%	4	N/A		1

9. Explore the common interest of faculty and research administrators to reduce obstacles.

	Response Percent	Response Count		Response Percent	Response Count
Level 1	15.6%	5	Level 4	12.5%	4
Level 2	43.8%	14	Level 5	3.1%	1
Level 3	25.0%	8			

Note. Responses were determined to have reoccurring themes and Table 1 is a representation of the responses received to the second and final survey.

Conclusions

There were recurring themes in the significant responses. The first theme addressed the system of research administration. Faculty expressed a need for assistance with preparing proposals, budgets and streaming procedures for timely proposal review. Such assistance could be in the form of mentoring or critiquing proposals. Faculty felt that research administrators should provide more help and be less focused on enforcing rules and regulations. Faculty believed that there are bottlenecks in the financial accounting and reporting of grants and that purchasing services should be provided in a more timely fashion. Faculty requested that time required to spend on paper work be reduced. Faculty suggested that research administration should add more temporary staff to assist in times of peak proposal submissions to alleviate the administrators' increased work loads.

The second theme reflected a desire for additional financial support for faculty research in the form of assistance with matching funds and a return of indirect cost to the department and Principal Investigators.

Better communication and teamwork between faculty and research administration emerged as the third theme. Faculty felt that research administrators should encourage investigators pursuing basic research, and help them identify funding agencies and programs beyond the basic distribution of lists of announcements and web site links.

The fourth theme suggested that faculty could assist research administration by showing respect and understanding. Faculty expressed some need to submit proposals with adequate lead-time, and to work as a team.

Some opinions that did not rate as highly significant in the final survey were: (a) faculty's sensitivity to research administrators' time and workload; (b) exploring the common interest of faculty and

research administrators to reduce obstacles; (c) faculty interacting with research administrators to bring their research to the attention of funding agencies;, (d) taking a non-aggressive, open-minded approach toward research administrators; (e) working with faculty to plan a long-term university-wide research strategy; and (f) learning to trust research administrators, appreciating their role in securing funding, seeing them as partners, and delegating.

These opinions are from research faculty participating in this Delphi study, and are supported by their substantial number of years in research. Future research will be conducted to obtain the perspective of research administrators with substantial numbers of years of experience. In this way viewpoints can be isolated and a determination made as to collective concerns, points of agreement, and disagreement. By then adding the perspective of the university administration, funding agency criteria for a model of a living system can be generated.

The study provided both positive recommendations as well as areas of organization and attitude of both faculty and research administrators needing improvement. There is still a great deal of effort required to bring about the desired changes. These recommendations are offered as guidelines for both faculty and research administrators to consider in developing a vision for creating a living system of mutual goals and objectives, respect, and cooperation.

References

Boyer P., & Cockriel, I. (1998). Factors influencing grant writing: Perceptions of tenured and non-tenured faculty. *The Journal of Research Administration,* 29(3), 61-68.

Christopher and Gordon Publishers. (1999). *Bringing schools back to life: Schools as living systems in creating successful school systems. Retrieved January 21, 2004, from http:*//steen.acuvejle.dk/ic/pdf_filer/bringing_schools_back_to_life.pdf

Department of Sustainability and Environment. (2007). *Effective engagement: Delphi study.* Retrieved May 9, 2007, from http://www.dse.vic.gov.au/DSE/wcmn203.nsf/LinkView/D7B9E063A2B4FFAFCA25707E00248822EBB2EB2F9035229BCA257091000BF7A6.

Federal government and higher education. (1960). Englewood Cliffs, NJ: Prentice-Hall.

Hu, Q., & Gill, G. (2000). IS faculty research productivity: Influential factors and implications. *Information Resources Management Journal*, 13(2).

Ikenberry, S.O. & Hartle, T.W. (2000). *Where we have been and where we are going: American higher education and public policy.* Washington, DC: American Council on Education.

Kennedy, D. (1993). Making choices in the research university. *Daedalus,* 122(4).

Management Concepts Incorporated. (1995). *Uniform administrative requirements for grants: OMB Circular A-102 and 2 CFR parts 215.* Vienna, VA: Author.

McMillin, L. (2004). Creating the "complete scholar": Academic professionalism in the 21st century. *Liberal Education*, 90(2).

Porter, R. (2004). Off the launching pad: Stimulating proposal development by junior faculty. *The Journal of Research Administration,* 31(1), 6-11.

Stigler, S.M. (1993). Competition and the research universities. *Daedalus,* 122(4), 157.

Institutional Challenges of Interdisciplinary Research Centers

Sherry Glied, Ph.D.
Professor and Chair, Department of Health Policy and Management
Mailman School of Public Health

Suzanne Bakken, D.NSc.
Alumni Professor of Nursing, School of Nursing
Professor, Biomedical Informatics

Allan Formicola, D.D.S.
Professor and Vice Dean, College of Dental Medicine

Kristine Gebbie, Dr.PH.
Elizabeth Standish Gill Associate Professor, School of Nursing

Elaine L Larson, Ph.D.
Professor and Associate Dean, School of Nursing
Professor of Epidemiology, Mailman School of Public Health
Columbia University School of Nursing
630 W. 168th Street
New York, NY 10032
212-305-0723; FAX: 212-305-0722
Ell23@columbia.edu

Authors' Note

Supported by The Center for Interdisciplinary Research on Antimicrobial Research, CIRAR, http://www.cumc.columbia.edu/dept/nursing/CIRAR/, funded by The National Center for Research Resources, P20 RR020616. We appreciate the input and feedback from Dr. Peter Bearman, Professor and Chair, Sociology Department, Columbia University.

Abstract

Interdisciplinarity has become the model of scholarly inquiry generally espoused by many who seek federal research funding. Interdisciplinary research centers pose challenges to academic settings and to investigators. In a conference of directors of diverse research centers at a single research university we found that the challenges facing centers and their universities fell into three major categories: fiscal sustainability, recruiting and retaining faculty, and leadership sustainability. These challenges are discussed, and institutional recommendations are proposed to address these challenges.

Key Words: Academic Health Centers, Interdisciplinary Research, Research Centers

Introduction

Throughout the academic and research community, interdisciplinary research has become a catch phrase (Giacomini, 2004; Robertson, Martin, & Singer, 2003). With the recent emphasis in the NIH Roadmap initiative (http://www.ncrr.nih.gov/roadmapnewsecir.asp) on interdisciplinary and translational sciences, interdisciplinarity has become the model of scholarly inquiry generally espoused by many who seek and receive federal research funding. Despite this, there are major gaps in our general understanding of interdisciplinary research

and how it can be successfully integrated and sustained in academic health science centers and universities (Mallon & Bunton, 2005).

Entities designated as interdisciplinary research centers abound in large universities and academic health centers, but in many settings the mantra of interdisciplinary research may be no more than lip service. Such centers have been described as follows (Committee on Facilitating Interdisciplinary Research, 2004):

> Some are bigger and intellectually more influential than some academic departments. Others are highly specialized and narrow. Some have existed for decades, others disappear after only a few years, and still others merge to create new units or emerge when one interdisciplinary unit is split. Some have retained their original purpose throughout their lifetimes; others have substantially shifted their academic focus. (p. 20)

Considerable ongoing resources and efforts are being expended in these research centers. Although they are highly variable in their goals, administrative structure, funding, and defined outcomes, it is likely that there are also many commonalities and potential interfaces or even overlaps among them. Unfortunately, however, those characteristics that are predictive of success of such centers have not been clearly articulated or codified. Research centers are different from other academic units, and are relatively independent of the existing structure of a university. This means that they can undertake innovative research agendas free of the regulations of accrediting organizations, the routine activities inherent in administering educational programs, and the obligations of participation in university administrative activities. They are – or are intended to be – interdisciplinary, so that they can support research teams that cross disciplinary and departmental lines and their members can conduct research that falls outside the established bounds of a disciplinary department. Finally, centers are problem-responsive. They arise to confront specific issues and concerns, drawing together faculty whose work addresses these problems.

Interdisciplinarity, independence, and responsiveness are the principle strengths and rationales for the existence of research centers. At the same time, these features present centers, and the universities that house them, with several distinct challenges. In this paper, we report on the results of a conference of directors of diverse research centers at a single research university that focused on the challenges facing centers and their universities and the factors predicting their success.

The Conference

In 2004, the National Institutes of Health allocated funds for exploratory centers in interdisciplinary research (http://www.ncrr.nih.gov/roadmapnewsecir.asp). One of the 21 centers funded was the Center for Interdisciplinary Research on Antimicrobial Resistance (CIRAR, http://www.cumc.columbia.edu/dept/nursing/CIRAR/). CIRAR's core research collaborative team includes persons from the disciplines of epidemiology, microbiology, pediatrics, infectious disease, nursing, economics, health policy, education, statistics, economics, informatics, and public health. The goals of this Center were not only to develop a research agenda that would have an impact on the global problem of antimicrobial resistance, but also to establish a vital, sustainable interdisciplinary research

process. Despite the recognized need for interdisciplinary collaboration in biomedical research, there are structural and cultural disincentives within the academic setting that must be overcome. Hence, we developed a series of strategic initiatives to systematically examine the structure, processes, and outcomes necessary for an interdisciplinary research center to thrive.

One of our first orders of business was to review bodies of literature from business, education and health care to adapt and develop our own definition of interdisciplinarity which could then be used to identify the competencies needed for successful interdisciplinary research practice. From this literature review an initial definition was developed and small modifications were made after field testing. We defined *interdisciplinary research* as any study or group of studies undertaken by scholars from two or more distinct scientific disciplines. The research is based upon a conceptual model that links or integrates theoretical frameworks from those disciplines, uses study design and methodology that is not limited to any one field, and requires the use of perspectives and skills of the involved disciplines throughout multiple phases of the research process. The process we used to address the definitional aspects of interdisciplinary research has been described elsewhere (Aboelela et al., 2007).

Our second strategic initiative was to convene a group of directors of interdisciplinary research centers in a half-day symposium to accomplish five aims: (a) identify characteristics essential to successful interdisciplinary research centers; (b) assess challenges in the operation of a research center and strategies to deal with these challenges; (c) discuss mechanisms for sustainability of centers (e.g. funding); (d) increase networking and communication among interdisciplinary research centers; and (e) exchange successful strategies for enhancing minority and gender balance in interdisciplinary research centers, as well as the balance of junior and senior researchers. Because no list of such centers existed at the University, we searched websites and polled departments and schools to identify relevant centers, using the following criteria: the center had to be interdisciplinary with a major research mission and have current external funding from the government, foundations, and/or professional organizations. We identified 65 centers across Columbia University that met these criteria and contacted directors either directly by telephone or email.

While there was some initial skepticism among directors and academic administrators about whether such a meeting would yield a useful outcome, the majority of center directors were enthused and supportive, noting that there was little opportunity for such interface. The forum was convened in November 2005 with 59 attendees from 29 different centers. Also in attendance was a project officer from NIH, the vice president of the university, and several deans. Eight center directors and two moderators, who also serve as center directors, formed two panels to lead discussions responsive to each of the aims of the forum, and there was considerable input from the entire audience. Three professional staff members took extensive notes, panels were audiotaped, and consistent themes were summarized at the end of the day by a skilled facilitator. Summarized below are the thematic challenges identified by participants, discussion regarding the interface of the centers and the university, and a summary of issues and recommendations that emerged from this conference.

The Challenges Identified

The following represents a qualitative summary of the discussion that ensued. Our review of the conference proceedings suggests that the challenges to success facing research centers fall into 3 categories (Table 1): fiscal sustainability, recruiting and retaining faculty, and leadership sustainability.

Table 1

Summary of Challenges Identified by Interdisciplinary Research Center Directors

Challenge	Specific Issues
Fiscal sustainability	Need to continue seeking external funding; Loss of indirect cost recovery between grants or with some funding agencies; Extensive negotiations needed for new resources such as space, personnel, administrative support; Bridge funding during short unfunded intervals (i.e., between grants)
Recruiting and retaining faculty	Some faculty do not fare well in an interdisciplinary environment; Willingness to learn new language and constructs of other disciplines; Need to satisfy disciplinary departmental promotion criteria; Changing faculty needs over the lifespan of a center; Providing incentives for faculty involvement (e.g., pilot funds); Varying expectations of roles across disciplines; No mechanism for hiring faculty outside an established department
Leadership sustainability	Administrative demands interfere with time for science; Maintaining a center when a founding charismatic leader leaves or changes

Fiscal Sustainability

Many, but not all centers at the university began with a substantial research grant. A small number began with funding from school or university administration or from an outside gift. This initial funding allowed the centers to become established and to embark on their programs of research, and also financed or enabled a request for space and other resources, such as administrative support.

Over time, center financing evolved. Successful centers generally obtained additional outside grant support to continue or enlarge their research programs. These new grants, however, often raised challenges for the centers, especially when they were written by faculty from disciplinary departments who had joined the center. The new grants brought indirect cost recovery (ICR) funds, the distribution of which among the university, schools, departments, and the center itself had not always been clearly contemplated at the establishment of the center. Centers often required new resources – space, faculty, or administrative support – and center directors complained that obtaining these resources sometimes necessitated extensive negotiation.

Policies with respect to the distribution of ICR funds varied considerably across the University. Center directors noted that the ability to maintain control of some ICR funds facilitated the task of maintaining the center over time. Centers with well-established protocols for sharing ICR with disciplinary departments also found that this practice brought them needed support from the departments. Centers without access to ICR funds, especially those without an outside endowment, had to develop strategies that would allow them to make longer term commitments to participating faculty.

In some cases, centers experienced an interval between grants when funding was insufficient to maintain core resources. Generally, centers did not have guaranteed sources of bridge funds for these circumstances. Those larger centers that both held many grants simultaneously and obtained a share of ICR funds sometimes had some wiggle room, but centers with fewer grants found it difficult to set aside a share of funds (from whatever source) and had to negotiate bridge funding. Center directors agreed that reliance on direct federal grant funding alone was problematic. They noted that having a diversified portfolio of financial supporters (including a combination of government, industry, foundations, endowment, and university funds directly or through ICR) helped provide stability.

Recruiting and Retaining Faculty

The initial development of a center generally required identifying faculty across disciplines with an interest in a topic area. Successful centers had identified research areas where there was a widely shared sense of need for more collaborative work. Several center directors remarked that they had been flooded with requests to participate when the center was first developed.

Challenges around faculty arose for three reasons. First, the center directors agreed, excellent disciplinary researchers committed to a problem area and excited by the prospect of collaborating with others may nonetheless fail to thrive in an interdisciplinary research environment. Centers depend on faculty who are both rigorous scholars and can function well in an institutionally unusual environment. They must be willing to learn the language and constructs of other disciplines. They must have, as one center director put it, a high level of intellectual curiosity, tolerance for ambiguity, and ability to play with others.

Center directors struggled with identifying such individuals and with the problems created by members who did not fit this bill. Some faculty members were simply not interested in spending the time necessary to work across disciplines or sharing their perspectives and research interests with others, i.e. they were not cut out for an interdisciplinary environment. Many found that younger faculty members were more malleable and fit into the center better than did more established scholars. The need to satisfy disciplinary department promotion criteria, however, can make participation in an interdisciplinary center difficult for junior faculty. Moreover, centers cannot function exclusively with young faculty. They need more senior faculty members to act as "heavy hitters" and obtain substantial grants, as well as to manage the administrative tasks of the center even though some may be less accommodating than junior faculty.

Second, centers needed to retain and replenish the ranks of their faculty over time. Center directors needed strategies for faculty recruitment and retention throughout the life of a center. They reported that the establishment of core facilities often acted as a magnet that drew and held faculty to the center. Many centers offered pilot grants and seed money to investigators.

Moving beyond pilot projects required new kinds of collaboration and communication among center members. Conference participants pointed out that such communication can be difficult. For example, the culture of the private sector where interdisciplinary collaboration has been most successful emphasizes discovery and application of profitable products, while academics may be more interested in mechanisms and new discoveries. In other cases, collaborators may have very different styles of communication, as well as different perspectives on sharing and ownership. Because of the nature of the work, some disciplines may have varying vocabularies and methods, expectations about the pace or hours to be worked and standards of proof. Some investigators favor rapid publication of each new finding; others prefer to amass a body of work for a single large publication. Some are open to large teams and data sharing while others prefer to minimize interactions. Thus, working and communication styles played important roles in attracting or failing to attract and retain faculty over time.

The need to recruit new faculty often generated a third problem. At this university, as at most others, only disciplinary departments may make faculty appointments and promotions. In some cases, centers may appoint researchers using non-professorial titles. Several center directors noted that these titles were less valued in the university than traditional titles. Center directors often needed to work with disciplinary department leadership to recruit faculty who were expected to participate exclusively in center activities. One center director suggested that permitting joint appointments between a department and a center might facilitate such recruitments.

In some cases, centers draw in most of the faculty of a given disciplinary department. The center may saturate a department with faculty. In these situations, the boundaries between the department and the center may disappear altogether. One university administrator noted that in this situation it might make more sense to convert the center into a department of its own.

Leadership Sustainability

The final set of challenges facing centers concerned leadership. Center directors must be charismatic advocates for their research areas and for the enterprise of interdisciplinary research. They must be able negotiators, finessing arrangements with university administrators, department chairs, and both accommodating and less accommodating center members. The nature of interdisciplinary work means that they must do all this in a collaborative rather than a dictatorial style. Finally, they must be skilled administrators. Several directors understandably complained that the administrative demands of managing a center were very time consuming.

Centers are generally developed because an individual with this rare combination of qualities initiates them. Problems may arise over time, however, when these pioneering leaders seek to share the burden of management or leave their positions. Center directors noted that new leadership was likely to be drawn from the ranks of senior center members who viewed this role as a professional obligation.

Centers and the Institution

All three of the challenges we identified arise from the problem of establishing the natural lifecycle of a center. Problem-responsive centers are fundamentally different from existing university institutions. They occupy a place between academic departments and individual grant-funded projects, both institutional forms with well-understood lifecycles. Our university, and we suspect most others, does

not have established criteria for defining when centers should be established, how they should be sustained, and when they should be closed. Individual grants are initiated by faculty and usually managed in the context of an academic department. They begin on the funding date and end (usually) when the grant expires. Financing, personnel, and leadership throughout the grant period are clearly specified in the grant proposal and funding statements.

Departments are developed very slowly. Generally, the formation of a department requires several layers of academic approval from the school, the university administration, the faculty senate, the board of trustees, and sometimes the State. To initiate a department, a school must clearly define the discipline represented, the teaching need and academic mission, and availability of appropriate resources to meet the articulated needs. Once established, a department is built on the financial and scholarly bedrock of its teaching mission. Sufficient faculty must, at the very least, be retained to teach courses required by accrediting agencies. These agencies, in turn, provide an outside force prompting the university to maintain the viability of the department. Teaching revenue, while often limited, provides a stable backstop against volatile outside "soft money" funding. Closing a department, a very rare event, likewise requires a series of steps, and the academic institution usually remains responsible for compensating any tenured faculty in a department that is closed.

Demands from students, accrediting agencies, and others, and the existence of teaching revenues, require that universities have well-established procedures for evaluating and maintaining their academic departments. Procedures exist to recruit faculty when positions become available, and to promote faculty through promotions committees. Universities also have procedures for recruiting departmental leadership, whether through a system of rotation or a search process. Finally, most universities have formal systems of departmental review, during which outside committees periodically assess the performance of each department.

Centers fall somewhere between individual grants and departments. They begin with much more university buy-in than would an individual faculty member's grant proposal. Since interdisciplinary research centers exist to address a new area of research, they do not require all the steps needed to establish a department. Centers generally have a specific mission statement and aims defining the proposed scope of the center. Unlike the case of a grant, however, this statement generally does not specify when the work of the center will be completed or what the criteria would be to close the center.

Research centers, unlike academic departments, often do not collect teaching revenue. Most depend on the school or university administration to help them maintain fiscal sustainability, either through ICR sharing or direct commitments. Without pre-specified guidelines about what constitutes center success and what the university's commitment to the center will be, center directors cannot always rely upon these potential funds. This lack of dependable funding leads center directors to seek independent endowment support. This, in turn, can pose challenges to the university if the rationale for the existence of the center no longer exists or if centers compete with other university priorities for outside funding.

Further, centers usually do not have a natural constituency, unlike departments, which can depend on their current students and alumni, as well as accrediting agencies,

to advocate on their behalf. Several of the center directors at our conference spoke of their efforts to develop a constituency in the outside community to provide them with leverage as they built their centers. An outside constituency relieves some of a center director's burden to continuously justify the university's commitment.

There is generally no established procedure for sustaining leadership in centers. In the case of a single grant, the life of the grant is coincident with the participation of the lead investigator. In the case of a department, the existence of the department is independent of the present leadership. In the case of a center, leadership and existence are intertwined. If a university has no systematic procedures for deciding when a center is successful or should be perpetuated, the decision to maintain leadership for a center is made separately in each case.

Centers should not be departments. They should come into and out of existence more easily and fulfill missions that departments cannot. But as centers become an increasingly important component of the university's institutional life, more formal procedures are needed to monitor their establishment, continuation, and termination. These procedures will help the university control its overall operations and ensure the quality of the centers. It will also help center directors, who will be able to rely on a set of defined privileges and obligations as they strive to build their faculties and research programs.

Summary and Recommendations

The process of collaboration requires institutional and individual commitment, but formal partnerships such as research centers are regulated primarily at the institutional level. Nearly all institutions have rules and guidelines for interdisciplinary research to govern ownership of work products and data, material transfer, and academic-industrial agreements. In general, external collaboration cannot proceed without involving the institution. Although guidelines or regulations do not explicitly cover many aspects of collaboration, the goal should be communication that clarifies expectations of all parties involved. For these reasons, policies, procedures and principles for management of interdisciplinary research centers need to be explicit.

The challenges of interdisciplinary research centers highlighted by participants in this conference—fiscal sustainability, recruiting and retaining faculty, and leadership—have been recently summarized in a report published by the National Academy of Sciences (2004). To our knowledge, however, our symposium was the first formal meeting of a large cadre of research center directors to address the aims we articulated. While there remain at many universities structural challenges to interdisciplinary research (e.g. policies and processes for sharing of ICR funds), we recognized that the major challenges as well as the major sources of gratification associated with research centers are interpersonal as well as institutional.

This conference served to facilitate and support an institutional shift towards an environment in which interdisciplinary efforts thrive. This is well within the ethos of the university whose faculty strive to work in collaboration with those outside of their own disciplines. Following this conference, a senior staff member was hired by the university to focus on the development and support of interdisciplinary research. Based on the proceedings of the conference, we make the following recommendations for institutions in which interdisciplinary research centers

are housed:(a) maintain a database of interdisciplinary research centers within a centralized office (e.g. grants and contracts or research office) for the purposes of networking and tracking; (b) provide an ongoing forum for interaction among directors and members of interdisciplinary research centers; (c) establish criteria for defining when centers should be established, how they should be sustained, and when they should be closed (i.e., what the natural lifecycle of a center should look like); (d) clearly identify individuals/offices within the institution that are responsible for policies regarding issues such as indirect cost sharing, faculty recruitment into centers and/or departments, and other administrative policies that influence center operations and success; (e) provide support for development of interdisciplinary leadership skills; (f) develop formalized mechanisms to assure that interdisciplinary activities are acknowledged and rewarded in the faculty promotion and tenure process; and (g) explore the role of interdisciplinary centers in developing and contributing to coursework designed to prepare researchers with interdisciplinary expertise.

References

Aboelela, S., Larson, E., Bakken, S., Carrasquillo, O., Formicola, A., Glied, S., et al. (2007). Defining interdisciplinary research: Conclusions from a critical review of the literature. *Health Services Research*, *42* (1Part 1), 329-346.

Committee on Facilitating Interdisciplinary Research, National Academy of Sciences, National Academy of Engineering, Institute of Medicine. Andreasen, N.C., & Brown, T.L. (2004). Committee on facilitating interdisciplinary research. In *Facilitating interdisciplinary research* (p. 20). Washington, D.C.: The National Academies Press.

Giacomini, M. (2004). Interdisciplinarity in health services research: Dreams and nightmares, maladies and remedies. *Journal of Health Services Research Policy,* 9, 177-183.

Mallon, W.T., & Bunton, S.A. (2005). Research centers and institutes in U.S. medical schools: A descriptive analysis. *Academic Medicine, 80*, 1005-1011.

Robertson, D.W., Martin, D.K., & Singer, P.A. (2003). Interdisciplinary research: Putting the methods under a microscope. *BMC Medical Research Methodology, 3*, 1-5.

Why Academics Have a Hard Time Writing Good Grant Proposals

Robert Porter, Ph. D.
Program Development Manager, Research Division
Virginia Tech
340 Burruss Hall, MC0244
Blacksburg, VA 24060
(540) 231-6747
reporter@vt.edu

Author's Note

This paper was presented as part of the 2006 Symposium at the annual October meeting of the Society of Research Administrators International in Quebec City, where it was awarded Best Paper of the Year.

Abstract

This paper discusses the contrasting perspectives of academic prose versus grant writing, and lists strategies grant specialists can use to help researchers break old habits and replace them with techniques better suited to the world of competitive grant proposals.

Introduction

When they are new to the grant game, even scholars with fine publishing records can struggle with proposal writing. Many are surprised to find that the writing style that made them successful as academics is not well suited to crafting a winning proposal. To succeed at grant writing, most researchers need to learn a new set of writing skills.

Academic Writing

For purposes of this discussion "academic writing" is defined as that style commonly adopted for scholarly papers, essays, and journal articles. The following is a typical example:

> Taken together with the findings from the present study that (a) workplace aggression in the primary job was more closely associated with negative work experiences and (b) both situational and individual characteristics played a role in aggression in the secondary job, future research might benefit from a greater focus on the subjective salience of the job as a moderator of the relationship between workplace experiences and supervisor-targeted aggression. Indeed, despite the differential effects of situational and individual difference factors on aggression, it is notable that the individual difference factors exerted a consistent but relatively low-level effect on aggression across contexts, whereas the more salient situational experiences exerted context-specific effects. (Inness, Barling, and Turner, 2005)

Look at the Difference

To start, glance at the first pages in any sampling of winning grant proposals. The first thing you notice is that they look different from pages in typical academic journals. Sentences are shorter, with key phrases underlined or bolded to make them stand out. Lists are printed bullet style. Graphs, tables and drawings abound. Now read the pages more carefully. The writing is more energetic, direct and concise. The subject matter is easy to understand, as there are fewer highly technical terms.

Each time you learn something about a subject entirely new to you. You are intrigued by exciting new ideas that have a good chance for success. In short, you quickly agree that the review panels made the right choices in funding these proposals.

The lesson here is a hard one for beginners: Success in grant writing is a matter of style and format as much as content. Make no mistake—the best written proposal will not win money for a weak idea. But it is also true that many good ideas are not funded because the proposal is poorly written (New & Quick, 1998; Steiner, 1988). Sometimes the failure is due to a weak or missing component that is key to a good proposal. The research plan may be flawed or incomplete. The evaluation methods might be inadequate. The researchers may not be qualified to carry out the work. But all too often, the core problem in a failed proposal lies in the writing itself, which bears too many characteristics of academic prose. (A baffled professor once came to my office bearing the written critiques he had received from reviewers of a failed proposal. One of them included this killer remark: "Reads like a journal article.")

Contrasting Perspectives

To understand the dimensions of the overall problem, consider the contrasting perspectives of academic writing versus grant writing:

Table 1

Academic Writing versus Grant Writing: Contrasting Perspectives

Academic Writing	Grant Writing
Scholarly pursuit: *Individual passion*	**Sponsor goals:** *Service attitude*
Past oriented: *Work that has been done*	**Future oriented:** *Work that should be done*
Theme-centered: *Theory and thesis*	**Project-centered:** *Objectives and activities*
Expository rhetoric: *Explaining to reader*	**Persuasive rhetoric:** *"Selling" the reader*
Impersonal tone: *Objective, dispassionate*	**Personal tone:** *Conveys excitement*
Individualistic: *Primarily a solo activity*	**Team-focused:** *Feedback needed*
Few length constraints: *Verbosity rewarded*	**Strict length constraints:** *Brevity rewarded*
Specialized terminology: *"Insider jargon"*	**Accessible language:** *Easily understood*

Scholarly Pursuit versus Sponsor Goals
Driven to make unique contributions to their chosen fields, scholars habitually pursue their individual interests, often with a good deal of passion. When seeking financial support for these endeavors, however, many find that potential sponsors simply do not share their enthusiasm. "A sound concept, but it does not fit our current funding priorities," or similar phrases, are commonly found in letters that deny funding. With the exception of a few career development programs, funding agencies have little interest in advancing the careers of ambitious academics. Sponsors will, however, fund projects that have a good chance of achieving *their* goals. This is why seasoned grant writers devote a good deal of time parsing grant program announcements, highlighting passages that express what the sponsors want to accomplish, and what kind of projects they will pay for. Then the writers adopt a service attitude, finding ways to adapt their expertise to match the sponsor's objectives. Finally, they test their ideas with grant program officers before deciding to write a proposal. As one of our university's consistently successful grant writers put it: "My epiphany came when I realized that grant programs do not exist to make me successful, but rather my job is to make those programs successful."

Past versus Future Orientation
In academic writing, the researcher is describing work that has already been done: Literature has been reviewed, an issue examined, a thesis presented, a discovery made, a conclusion drawn. Grant writers, by contrast, describe in detail work that they wish to do. For some disciplines, good grant writing can be viewed as science fiction, i.e., it must be grounded in solid science, but the research design itself is a set of logical yet imagined activities that have yet to take place. This in itself is a major shift in perspective that seasoned scholars find difficult when starting to write proposals.

Theme-Centered versus Project-Centered
Scholarly writers are prone to dwell on theme, thesis and theory. Essays and books can be devoted to the authors' original thinking, contributions of past and present scholars, or the evolution of entire schools of thought. They draw us into the realm of ideas. Grant writers, however, draw us into a world of action. They start by sketching out an important problem, then they move quickly to describing a creative approach to addressing that problem with a set of activities that will accomplish specific goals and objectives. The overall project is designed to make a significant contribution to a discipline or to a society as a whole.

Academic writers often seek funding to "study," "examine," or "explore" some theme or issue. But this can be deadly, as sponsors rarely spend money on intellectual exploration. They will, however, consider funding *activities* to accomplish goals that are important to them. It is the project that interests them, not just the thinking of the investigator. Finally, academic essays end with their authors' final conclusions, while grant proposals end with their projects' expected outcomes.

Expository versus Persuasive Rhetoric
The academic writer uses language to explain ideas, issues and events to the reader. The aim is to build a logical progression of thought, helping the reader to share the writer's intellectual journey and to agree with the core themes of the piece. But the language in a grant has to be stronger; it must sell a nonexistent project to the reader. The writer has to convince the reviewer that the proposed research is uniquely deserving. The whole effort is geared toward building a winning argument, a compelling case that scarce dollars should be spent on a

truly exceptional idea that has an excellent chance for success. Grant reviewers are a notoriously skeptical lot who reject a majority of proposals, so writers must use language strong enough to win their reluctant support. In effect, a good proposal is an elegant sales pitch.

Impersonal versus Personal Tone
From their undergraduate term papers to their doctoral dissertations and numerous papers that followed, scholars have been conditioned to generate prose in proper academic style—cautious, objective and dispassionate, exclusively focused on the topic, with all evidence of the writer's persona hidden from view. Grant writers, however, seek the reviewers' enthusiastic endorsement; they want readers to be excited about their exemplary projects, so they strive to convey their own excitement. They do this by using active voice, strong, energetic phrasing, and direct references to themselves in the first person. Here are some examples:

> Our aim with this innovative curriculum is to improve the supply of exceptionally skilled paramedics with National Registry certification.
>
> This project will provide your grant program with a powerful combination of cutting edge nanoscale science and frontier research in applied geochemistry.
>
> Though we launched this large and ambitious program just two years ago, we are gratified by the regional and national awards it has garnered.

Sentences like these violate editorial rules of many scholarly journals.

Solo Scholarship versus Teamwork
With the exception of co-authored work, academic writing is mostly a solo activity. Perched at a desk, in the library or at home in the den, the solitary scholar fills page after page with stolid academic prose. When the paper or book chapter is completed, it may be passed to one or two readers for final proofing, but the overall endeavor is highly individualistic. Good grant writing, however, requires teamwork from the outset. Because their ultimate success depends upon nearly unanimous approval from a sizeable group of reviewers, grant writers place high value on feedback at every phase of proposal writing. Before the first draft, a thumbnail sketch of the basic concept will be sounded out with colleagues before sending it on to a grant program officer to test whether the idea is a good fit. Large multi-investigator proposals are typically broken into sections to be written and rewritten by several researchers, then compiled and edited by the lead writer. Many large proposals are submitted to a "red team" for internal review before sending them out to the funding agencies. Even single investigator proposals have been combed over repeatedly as the documents move from first draft to the final product. Proposals that bypass this essential process have a much greater chance of failure.

Length versus Brevity
Verbosity is rewarded in academe. From extended lectures to journals without page limits, academics are encouraged to expound at great length. A quick scan of any issue of *The Chronicle of Higher Education* reveals the degree to which simple ideas can be expanded to multiple pages. A common technique is to stretch sentences and paragraphs to extreme lengths. Consider the following example, which won a Bad Writing Contest sponsored by the journal *Philosophy and Literature:*

> The move from a structuralist account in which capital is understood to structure social relations in relatively homologous

> ways to a view of hegemony in which power relations are subject to repetition, convergence, and rearticulation brought the question of temporality into the thinking of structure, and marked a shift from a form of althusserian theory that takes structural totalities as theoretical objects to one in which the insights into the contingent possibility of structure inaugurate a renewed conception of hegemony as bound up with the contingent sites and strategies of the rearticulation of power. (Butler, 1997)

An extreme example perhaps, but its characteristics can be seen in many scholarly essays.

Grant reviewers are impatient readers. Busy people with limited time, they look for any excuse to stop reading. They are quickly annoyed if they must struggle to understand the writer or learn what the project is all about. Worse, if the proposal does not intrigue them by the very first page, they will not read any further (unless they must submit a written critique, in which case they immediately start looking for reasons to justify why the proposal should not be funded). When asked to describe the characteristics of good grant writing, senior reviewers put qualities such as "clear" and "concise" at the top of the list (Porter, 2005). Brevity is not only the soul of wit; it is the essence of grantsmanship. Or, to cite Mies van der Rohe's famous dictum about modern architecture: "Less is more."

Specialized Terminology versus Accessible Language

Every discipline uses specialized terminology, much of it dictated by the need to convey precise meaning. But there reaches a point where specialized words become needlessly complex and the reader becomes lost in a tangle of dense verbiage. As Henson (2004) points out, a spell comes over us when we know our writing will be evaluated, either by editors or by grant reviewers: We want our work to appear scholarly, so we habitually inflate our prose with large words and complicated sentences to achieve the effect of serious thinking. Unfortunately, such tactics have the opposite effect on readers. Alley (1996) shows how too many big words and convoluted expressions can result in muddled jargon:

> The objective of this study is to develop an effective commercialization strategy for solar energy systems by analyzing the factors that are impeding commercial projects and by prioritizing the potential government and industry actions that can facilitate the viability of the projects.

A sentence like this could kill a grant proposal on the first page. Grant writers cannot afford to lose even one reviewer in a barrage of obtuse phrasing. They must use language that can be understood by a diverse group of readers, some of whom may be as highly specialized as the writer, but most will be generalists. Reworking the cumbersome structure above, Alley comes up with simpler, more accessible language:

> This study will consider why current solar energy systems have not yet reached the commercial stage and will evaluate the steps that industry and government can take to make these systems commercial.

Fewer words with greater clarity—a tradeoff that will improve the score of any grant proposal. But how can one consistently strike a balance between scholarly precision and meaning that is clear to a mixed audience? One NIH web site on grant writing advises writers to study articles published in *Scientific American* (National Institute of Allergy and Infectious Diseases [NIAID], 2006). Here world class scientists use accessible language to teach a general

readership about complex subjects while simultaneously informing them of cutting edge developments. Good proposals do the same. The following excerpt is from a recent *Scientific American* article on stem cells and cancer research:

> Conventional wisdom has long held that any tumor cell remaining in the body could potentially reignite the disease. Current treatments therefore, focus on killing the greatest number of cancer cells. Successes with this approach are still very much hit-or-miss, however, and for patients with advanced cases of the most common solid tumor malignancies, the prognosis remains poor. (Clarke & Becker, 2006)

Clinically accurate yet easily understandable, this would be a fine introduction to a grant proposal.

Remedial strategies

Given the contrasting perspectives listed above, what can the university research office do to help academics adapt to the unfamiliar standards of grant writing? First, recognize that no one likes to be told they do not write well, especially highly educated folk who are justly proud of their intellectual achievements. Nevertheless, proactive and tactful research administrators can do much to help instill good proposal writing habits. Here are five remedial strategies that instruct without offending.

1. Home-Grown Workshops

For young investigators, grant writing workshops are an effective way to learn good writing techniques. Home-grown workshops, taught by any combination of research office personnel and grant-savvy faculty, can yield positive returns at a very low cost. Beginning workshops on basic grant writing skills should be offered on a regular basis, supplemented periodically by those focusing on specific funding agencies. Especially popular are presentations by successful grant writers and copies of winning proposals (Porter, 2004).

2. Reading Successful Proposals

Winning grants teach by example. By perusing several, the new grant writer will note some common differences from accepted academic style, and can be encouraged to mimic them. Successful proposals from one's own institution can be put online, with access limited to internal researchers. Copies of winning proposals can also be purchased from The Grant Center at reasonable rates: www.tgcigrantproposals.com. Finally, successful proposals can be obtained directly from federal agencies under the Freedom of Information Act, but be prepared to wait several months for the documents to arrive, with sensitive information deleted.

3. Editing by a Grants Specialist

While no amount of editorial polishing can save a weak idea, a seasoned grant writer can add value to a sound concept by judicious editing. This is labor intensive at first but once the writer catches on to the simpler, livelier style of grant writing, the need for personal attention drops off rapidly.

4. Red Team Reviews

Writing a strong proposal for a major multidisciplinary grant is a challenging project all by itself, one that can overwhelm the researchers, for whom grant writing is often an additional chore on top of full workloads. One effective tool is to form an internal review team consisting of experienced senior colleagues. If carefully selected for their expertise and reputations, their written comments can have great impact. Be warned, however: A considerable degree of gentle but persistent nagging is required for the writers to have the

document ready for internal review with sufficient lead time before the sponsor's deadline.

5. Writing Tips

Finally, the research office should post a set of simple writing tips on its web site. These are most helpful if examples of bad writing are contrasted with effective revisions. Seeing them side by side, readers will quickly spot which bad characteristics are their own, and will note how they can craft better versions. Alley's work, in particular, is peppered with numerous examples of weak composition contrasted with more effective phrasing. A truly time tested source is Strunk and White's familiar Elements of Style (2000). Versions of this concise, lively handbook have been popular for nearly half a century, and its instructions for crisp and vigorous writing will give heart to academics who are trying to break old habits.

Conclusions

As competition intensifies for limited research dollars, proposal success rates for most agencies are declining. To be successful in this environment, proposals must be written in a strong, persuasive style, and academic writers accustomed to a different style need help to develop more effective writing habits. Such leadership can be provided by a proactive research office that is sensitive to this pervasive need.

References

Alley, M. (1996). *The craft of scientific writing* (3rd ed.). New York: Springer.

Butler, J. (1997). Further reflections on the conversations of our time. Diacritics, 27(1), 13-15. Cited in Dutton, D. (1998). *Philosophy and Literature* announces winners of the fourth bad writing contest. Retrieved June 5, 2006, from http://www.aldaily.com/bwc.htm

Clarke, M., & Becker, M. (2006). Stem cells: The real culprits in cancer? *Scientific American*, 295(1), 53-59.

Henson, K. (2004). *Grant writing in higher education*. Boston: Allyn & Bacon.

Inness, M., Barling, J., & Turner, N. (2005). Understanding supervisor-targeted aggression: A within-person, between-jobs design. *Journal of Applied Psychology,* 90(4), 731-739.

National Institute of Allergy and Infectious Diseases. (2006). *How to write a grant application*. Retrieved June 20, 2006, from www.niaid.nih.gove/ncn/grants/write/index.htm

New, C. C., & Quick, J. A. (1998). *Grantseeker's toolkit*. New York: Wiley.

Porter, R. (2004). Off the launching pad: Stimulating proposal development by junior faculty. *The Journal of Research Administration*, 35(1), 6-11.

Porter, R. (2005). What do grant reviewers really want, anyway? *The Journal of Research Administration,* 36(2), 47-55.

Steiner, R. (1998). *Total proposal building*. Albany, N.Y.: Trestletree.

Strunk, W., & White, E. B. (2000). *Elements of style* (4th ed.). New York: Longman.

Internal Grant Competitions: A New Opportunity for Research Officers to Build Institutional Funding Portfolios

Rengarajan V. Balaji, MS, MBA, CRA,
Research Grants Development Coordinator
232 Grosvenor Hall
Ohio University College of Osteopathic Medicine
Athens, OH 45701
Phone: 740-593-2304
Fax: 740-593-2320
E-mail: balaji@ohio.edu

Christine Knisely, MA
Executive Director
Office of Research and Grants

Jack Blazyk, PhD
Associate Dean for Research and Grants
Office of Research and Grants
Ohio University College of Osteopathic Medicine,
Athens, OH 45701

Authors' Note

The material presented in this manuscript is not based on any presentation or dissertation. To the authors' best knowledge, no financial or other conflicts of interest exist, including specific financial interests and relationships and affiliations relevant to the subject of their manuscript. The competitive grant program described in this article was funded by the College of Osteopathic Medicine at Ohio University. The authors wish to thank Dean Jack Brose, D.O., and the College's Research and Scholarly Affairs Committee for their strong support in implementing this program. The authors also wish to thank Jessica Wingett and Suzanne Vazzano for their administrative support.

Abstract

The Ohio University College of Osteopathic Medicine in 2005 created an innovative competitive grant program aimed at stimulating faculty to submit more and better NIH research proposals, thereby increasing the probability of success. In this internal competition, three experienced external reviewers critique each proposal and assign a priority score, mirroring the NIH review process. An internal panel then selects the two to three best proposals to receive $20,000 awards, contingent upon submission to NIH of a revised proposal that incorporates the comments and suggestions of the reviewers. Thus, the awardees receive additional resources to move their project forward. Moreover, all participants benefit from the constructive reviews, the "free" review cycle (in addition to the NIH "three-strike" system), and the excellent learning experience in grant preparation, revision and submission of competitive proposals. Academic researchers and administrators, particularly at smaller, less research-intensive institutions, today face a challenging environment with increased competition for a limited funding pool. Under such circumstances, an internal grant development program may be a great avenue for mentoring and education for faculty, and

also serve as a cost-effective investment for research officers to increase external research funding as well as enhance the research skills of faculty.

Key Words: Grant, NIH, research administration, mentoring program, seed money

Introduction

The National Institutes of Health (NIH), the predominant funding agency for biomedical research in the United States, was allocated $29.24 billion for its fiscal year 2007 budget, an inflation-adjusted decrease of 1.2% from the previous year (National Institutes of Health, 2007). At the same time, NIH expects the number of grant proposals to increase by 6.5% in 2007 (Zerhouni, 2006). This is compounded by the decline in success rates for new NIH R01 research grants from about 25% in 1998 to 16.3% in 2006 (NIH, n.d.). At the same time, many academic institutions are attempting to increase federal research grant funding. For smaller, less research-intensive institutions, the situation is even more challenging if they are to compete with their more research-intensive counterparts.

Funding decisions at NIH are based primarily on the critiques provided by the reviewers who serve on study sections. While this system is necessary to ensure that only the best and most worthy proposals are funded, it can be a slow process. With the Roadmap program, NIH is streamlining the application process and encouraging more applicants by revising the review criteria, transitioning to the electronic grant application system and introducing a new award mechanism targeted toward beginning investigators (NIH, 2004, NIH, 2006 & NIH, n.d.). Despite these efforts, the average turnaround time between grant submission and receipt of scores and reviews is still five to seven months (NIH, n.d.). Typically, NIH grant programs permit a maximum of two resubmissions. Because the overwhelming majority of new proposals do not get funded during the first review cycle, it is not uncommon for applicants to spend up to two years revising and resubmitting their proposals before receiving a final decision on funding. In the absence of sufficient institutional support, this time lapse can significantly hinder a research project.

Sufficient preliminary data to demonstrate the feasibility of the applicant's hypothesis is one of the key factors that increase reviewers' enthusiasm for a grant proposal. In a proverbial Catch-22, however, limited resources can delay or prevent the generation of preliminary data required for a successful proposal. Hence, it would be helpful to have a targeted source of funding for a promising proposal that may not be funded in the first submission.

This article describes a novel competitive grant program that we believe can help address some of the problems discussed above. Faculty compete for $20,000 awards by submitting NIH research grant proposals for internal review. Our program is intended to increase both the quantity and quality of grant proposals submitted to NIH and to provide incentives to enhance chances of funding in a timely manner. Similar programs can be adapted and further customized to meet the needs and objectives of individual institutions.

The Program at OU-COM

The Office of Research and Grants at the Ohio University College of Osteopathic Medicine (OU-COM) initiated a program to stimulate the submission of competitive NIH proposals. The aim of this new mechanism is to support selected faculty in continuing their research and gathering more

preliminary data while their proposals are under review.

Participating faculty are required to complete a full research grant proposal using the NIH application format. These proposals are then sent to qualified external reviewers from across the nation. Reviewers are recruited with not only the necessary expertise in the scientific area of the grant proposal, but also with a track record of NIH funding and experience with the NIH review system. The reviewers, who are paid a modest honorarium, are instructed to critique the proposals based on NIH's standard review criteria and to assign a priority score, just as they would do as part of an NIH study section. The call for proposals is sent to faculty during the summer (July/August), with milestones and deadlines set in such a way that the applicant will be able to complete a significantly revised version of the proposal for submission to NIH during the February/March cycle of the following year.

Based on the critiques provided by the external reviewers, an internal panel of NIH-funded faculty members at Ohio University recommends up to three proposals for $20,000 awards, using funds allocated by the College. Because this award is restricted to OU-COM's faculty members, any potential conflicts of interest were minimized by recruiting panel members from outside the college. The $20,000 awards, coupled with the prospect of receiving expert reviews prior to submission to NIH, provide a strong incentive for faculty members to take part in the program.

When the competition was initiated in 2005, eight applications were received, of which three were selected for the internal award. Of these three, two proposals received respectable priority scores at NIH (160-175 range), but were not funded and one was unscored, ranking in the bottom half of the applications.

In 2006, the number of applications increased to 12, and two were selected for the award. These applications were revised and submitted to NIH for grant deadlines in early 2007; NIH review of these proposals is pending. We strongly encourage the faculty who did not receive internal college funding to use the reviewers' critiques to strengthen their proposals prior to submission to NIH.

Discussion

More and more faculty at smaller academic institutions are abandoning efforts to secure federal research funding because of increased teaching loads, stark competition for an ever-diminishing pool of grant monies, and lack of resources to generate the strong preliminary data required to produce competitive grant proposals. It is, therefore, important to provide assistance and incentives to faculty, so they can focus and refine their research efforts, and increase their chances for success in securing external research grant funding. Institutions faced with this situation may be well-advised to consider a competitive internal grant program, such as the one described here.

Why is this Program Important for Research Offices and Administrators?

The basic concept of internal grant funding opportunities to help investigators garner preliminary data is not unique. Many universities and medical schools (including University of Iowa Medical School, University of Minnesota Medical School, Georgia State University, University of Mississippi, Auburn University and University of Texas) have similar programs. However, there are certain important distinctions between existing programs

and OU-COM's. The key innovations of our program are: (a) by mirroring NIH's requirements, duplication of efforts during grant submission is avoided, making the grant review and submission process more efficient for both the research office and the researcher; (b) of the internal funding mechanisms that were identified, none had a requirement of an external grant submission tied to the program, nor did the proposals go through a rigorous external review process; and, (c) the scope of many of these funding mechanisms was limited, e.g., some were restricted to a particular research topic or to junior faculty members.

Additionally, our experience shows that there are a few overarching advantages to conducting such a program:

1. *Opportunity for mentoring and education*: One of the primary functions of research/grant offices is to educate and mentor investigators in grant submission and compliance with sponsors' regulatory, scientific and administrative requirements. A competitive grant program can serve as a good "dry run" for novice investigators who do not have significant NIH grant writing experience. This allows them to experience all of the elements of the grant application process — preparing biosketches, formulating a budget, following the sponsor's guidelines, assembling the various sections of the grant, honing writing and communication skills, and developing proficiency in using the electronic grant application system. Finally, the reviewers' critiques are also a key part of this education because they examine the soundness and value of the fundamental hypotheses, and the aims and methods of the project.

2. *Reduced review turnaround time and greater efficiency:* The elapsed time between proposal submission and applicants' receipt of critiques from external reviewers through this program was only two months, which is a 60-70% reduction in the average review time at NIH. The program is designed so that proposals can be revised based upon the reviews received in December and submitted to NIH for the February/March deadline dates.

3. *Improvement in quantity and quality of proposals*: A competitive grant program, coupled with institutional expectations, can provide the necessary incentive for faculty to apply for more grants *(quantity)*. With critiques from qualified and experienced reviewers, faculty can revise their proposals prior to submission for external funding and greatly improve their chances of funding by submitting a better proposal (quality).

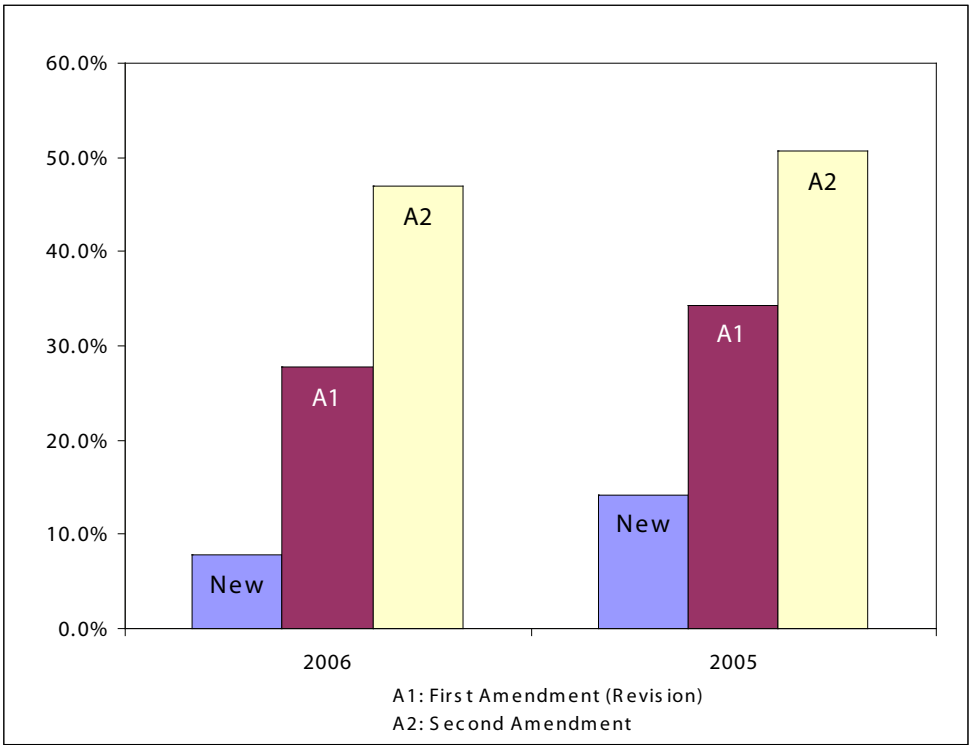
4. *The "fourth strike":* Many funding agencies have restrictions on the number of times an application can be submitted. At NIH, a research grant application can be revised only twice. If the application is unsuccessful after three attempts, NIH requires applicants to submit a new grant (making major changes in specific aims and research plans) for future applications. Given NIH's "three-strike" system, this grant competition program provides one additional review cycle (the "fourth strike") to improve the chances of funding.

5. *Resources to advance the research project:* Participants who receive $20,000 awards through the grant competition are able to advance their projects and gather more preliminary data, serving to jumpstart the project if funded by NIH or further strengthen a resubmission if the proposal is not funded. For example, one of the researchers selected for the award was

able to obtain enough preliminary data (using the awarded funds) to publish the results in a peer-reviewed publication, thus further strengthening his NIH grant application.

The success rates for new, first amendment and second amendment R01 proposals at NIH for 2006 are 7.9%, 27.7% and 46.9%, respectively (Figure 1) (Bleakley, personal communication, 2007). These data clearly show that subjecting a grant to a thorough review and revision, and subsequently resubmitting it considerably increases one's chances of being funded.

Figure 1.
Overall Success Rates for New and Amended R01 Proposals at NIH.



The key to the success of the grant competition lies in the ability to recruit qualified reviewers who can provide a thorough critique of the grant proposals; only then can the program truly simulate the stringent review process at NIH. Reviewers, who can comment not only on the technical aspects of the proposal but also provide valuable insight from a study section's standpoint, can significantly increase the likelihood of funding. In this regard, our program has been fortunate. The external reviewers who participated in this program were not only well-qualified to review the technical and administrative aspects of the grants, but also showed a strong sense of collegiality and responsibility – a genuine desire to do a thorough job and provide valuable input for the benefit of their fellow junior researchers. This was well- received and appreciated by the applicants of the grant competition; the high-quality reviews proved to be just as valuable an incentive as the $20,000 award, as indicated by the strong increase in the number of submitted proposals in the second year of the competitive program.

Process

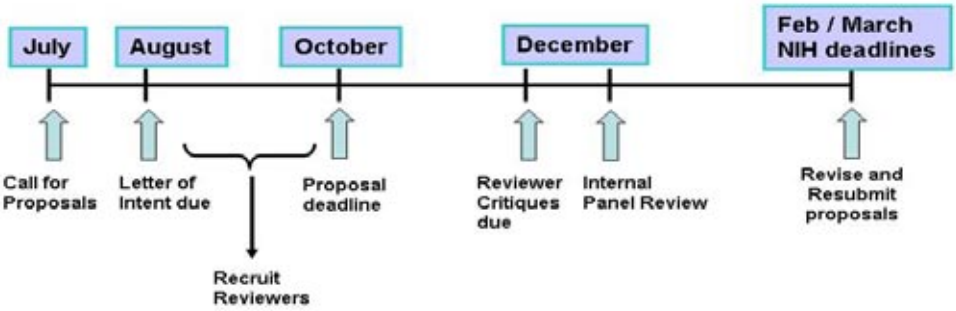
Creation and Implementation

The OU-COM grant competition was created in 2005, shortly after the announcement of an institution-wide initiative for enhanced national prominence in the areas of research and grant funding. While there was strong administrative support for the program, the faculty were initially less enthusiastic, but have shown increasing support since the first funding cycle. The goal of this program is to stimulate productivity and to provide a process through which faculty members improve the quality of their grant proposals. As mentioned earlier, the key to the success of this program was the quality of the external reviewers who had the required scientific background and also understood the NIH review process. Significant time and effort were spent in recruiting at least two qualified reviewers per proposal. For more broadly -defined research topics, three reviewers were recruited for each proposal. Online web resources such as PubMed, CRISP database and NIH Study Section rosters were used to identify and recruit potential reviewers. To maintain anonymity and to make the process fair, the identity of the reviewers was not disclosed to the applicants. The proposals were sent to reviewers after obtaining a signed confidentiality agreement. All reviewers were instructed to prepare a detailed critique of the proposal, conforming to NIH's review criteria. A modest honorarium was paid to reviewers for these services. This grant competition program was developed and administered by the Office of Research and Grants at OU-COM.

Timeline

A call for proposals was sent during the last week of July or the first week of August (see Figure 2 for complete timeline). All faculty members interested in responding to the call were instructed to provide some basic information pertaining to their proposal (i.e., topic of research; tentative title; program announcement number, if applicable; NIH grant mechanism; etc.). Using this information, suitable reviewers were recruited. The deadline for faculty to submit proposals was the second week of October, with reviews completed by early December. Thus, the applicants had sufficient time to revise their proposals and submit them to NIH for the February/March deadlines.

Figure 2.
Timeline for the OU-COM Grant Competition.



Reflections

The most valuable product of the grant competition was the high-quality of the reviews, which provided thorough and constructive suggestions for strengthening the proposals. It was impressive to find that most reviewers were willing to devote time from their busy schedules, to prepare detailed critiques and to provide pointers for their fellow researchers' benefits. In fact, a few reviewers even volunteered to provide additional assistance to the applicant beyond the scope of this program. Such a conscientious effort on the part of the reviewers was a major contribution to the success of this program, and, in many cases, was more valuable than the monetary awards.

Based upon our experience over the last few years, we believe that this grant competition program could be further improved in several ways. First, we could perform a preliminary review of the proposals before they are submitted to the external reviewers. Through this process, proposals could be screened for completeness, for adherence to NIH's guidelines (i.e., page limitation; font size and type; biosketches; introduction section; budget justification; human subjects and animal sections; etc.), and for formatting and grammatical errors. Correcting such errors before sending out the proposals will allow the reviewers to focus on scientific merit with fewer distractions, thereby resulting in more useful comments. Secondly, a more rigorous follow-up process is required. To gain the greatest value from the reviewers' comments, faculty should have the opportunity to work closely with the research office staff during the revision process. Faculty whose proposals were not selected for an award should also be urged to make revisions. After revision, these proposals may be as competitive in the NIH review process as those selected for the internal awards.

Conclusion

A competitive internal grant program such as the one started at OU-COM can help to enhance the research climate within an institution, stimulate faculty morale, and encourage friendly competition and productive collaboration among faculty members. Our experience with this program has been encouraging, as evinced by the 50% increase in the number of applications over the last two years. While supporting such a program requires a significant institutional commitment in terms of both time and money, we believe that this investment will prove to be worthwhile because of the potential to increase both the research skills of our faculty and the level of external research funding.

References

NIH establishes website for new investigators. (2004). Retrieved December 25, 2006 from http:/www.nih.gov NOT-OD-05-014.

NIH Extramural Nexus. (2007, March). Retrieved May 15, 2007 from http://grants.nih.gov/grants/partners/0307Nexus.htm

NIH Office of Extramural Research. (n.d.). *Submission dates for competing applications*. Retrieved January 10, 2007 from http://grants1.nih.gov/grants/funding/submissionschedule.htm. Standard postmark/

NIH successfully receives grant applications electronically through GRANTS.GOV. (2006, January). *NIH Extramural Nexus*.

NIH success rates by type and activity. (n.d.). Retrieved August 29, 2007 from http://grants.nih.gov/grants/award/success/Success_ByActivity.cfm

Zerhouni, E.A. (2006). Research funding. NIH in the post-doubling era: Realities and strategies. *Science, 314*(5802), 1088-1090.

Application of Standard Project Management Tools to Research – A Case Study from a Multi-national Clinical Trial

Peter Gist, Ph.D.
Ove Arup & Partners Ltd, UK
peter.gist@arup.com
Ove Arup & Partners Ltd
13 Fitzroy Street
London W1T 4BQ, UK

David Langley, Ph.D.
Director of Research and Enterprise Development,
University of Bristol, UK

Authors' Note

We recognise the contribution and efforts of a number of key individuals whose work on MDP ensures it is such a well-managed study and who were intimately involved in the development of the tools and reports described in this paper: Dr. Sheena McCormack (MDP Chief Investigator), Professor Janet Darbyshire, Emmanuel Harding, Terry Kenvyn, Clare Rutterford (all from Medical Research Council Clinical Trials Unit, UK), Professor Jonathon Weber, Dr. Lorna Colquhoun, Kathryn Taylor, Ruth Tipples, Claire Puddephatt (all from Imperial College London, UK), Professor Helen Rees (Reproductive Health and HIV Research Unit, University of Witwatersrand, South Africa), Professor Heiner Grosskruth (MRC/Uganda Virus Research Institute, Uganda), Stephen Phillips, Andrew Butt (both from Ove Arup & Partners Ltd, UK), investigators and staff at the trial sites in Africa too numerous to mention by name. MDP is jointly funded by the UK Department for International Development and Medical Research Council, UK. David Langley was previously Director of Research Services, Imperial College London, UK.

Abstract

PRINCE2, which stands for Projects in Controlled Environments, is a project management method covering the organisation, management, and control of projects and is widely used in both government and commercial IT and building projects in the UK. This paper describes the application of PRINCE2 to the management of large clinical trials (specifically, of a Phase III trial of a candidate microbicide to prevent vaginally acquired HIV infection). It reviews the challenge of ensuring that the project management tools add value to the project overall and are not perceived as an overly administrative burden. It reviews the requirement for high level summary reports for use by an executive committee and funding bodies, highlighting the reasons for taking this approach — in particular, not only to manage the science, but to link expenditure to activities at geographically separate trial sites and to key performance indicators, and to provide tools for monitoring risks and possible re-alignment of budgets to reflect changing activities and outputs by collaborators. The paper considers the wider costs and benefits to researchers and funders of taking this approach and explores implications for research administrators and managers at institutions involved in large, complex collaborative research projects, whether clinical or not.

Key Words: Project management tools, PRINCE2, clinical trial, microbicide, Microbicides Development Programme (MDP), financial controls

Introduction

Although the pharmaceutical industry has well-developed project management methodologies for research, it is unusual for academic researchers working in the education and public sectors to do so. The discipline that these tools impose can appear alien initially and often require cultural change for the potential value they can bring to be recognised.

This paper examines the experience of introducing a standard project management tool, PRINCE2, to the management of a large Phase III clinical trial, the Microbicides Development Programme (MDP). Phase III clinical trials are usually undertaken by the pharmaceutical industry. Somewhat unusually, the MDP is publicly funded and managed by a partnership of academic bodies. Funding is provided by the UK Department for International Development (DFID) and the programme is coordinated by the Medical Research Council Clinical Trials Unit, UK and Imperial College London, UK. The trial sites themselves are in Africa.

The complexity of this particular trial, and the need to communicate and monitor progress against budget in a standard format to the funder, DFID, prompted senior academic staff to modify their approach to management and reporting through adopting elements of PRINCE2. This has proved beneficial for both the trial team and DFID.

The paper describes what was done in the MDP case and discusses the costs and benefits of adopting a similar approach more widely in conducting academic-led clinical trials.

The Microbicides Development Programme

The Microbicides Development Programme (MDP) is a partnership to develop vaginal microbicides for the prevention of HIV transmission, funded by the UK Department for International Development (DFID) and the UK Medical Research Council, and coordinated by the Medical Research Council Clinical Trials Unit, UK and Imperial College London, UK. The central goal of the Partnership is to complete a Phase III trial of candidate microbicides in Africa. Phase III trials are randomised controlled trials on large patient/healthy volunteer groups (often enrolling several thousand individuals), and are aimed at definitively assessing the efficacy of a new therapy or prevention. Phase III trials are invariably expensive, time-consuming and complex to design and run. These trials look at whether the new treatment works and at any side effects it may cause.

The MDP budget is GBP 42M (USD 75M) and involves thirteen principal scientific partner institutions, six of which are African. A large number of scientists and clinicians are involved in programme management functions in addition to their own areas of particular expertise. There are also a number of people focusing on specific areas, such as trial management and communication.

Given the size of the management "burden" of a Phase III clinical trial and the need to communicate progress in a standard format to the funder, DFID, in a way that would reflect both the customary approaches to trial management and DFID's usual approach to reporting on projects (not designed specifically for clinical trials), senior academic staff opted to adopt an approach to project management based on PRINCE2 methodology.

Features of PRINCE2

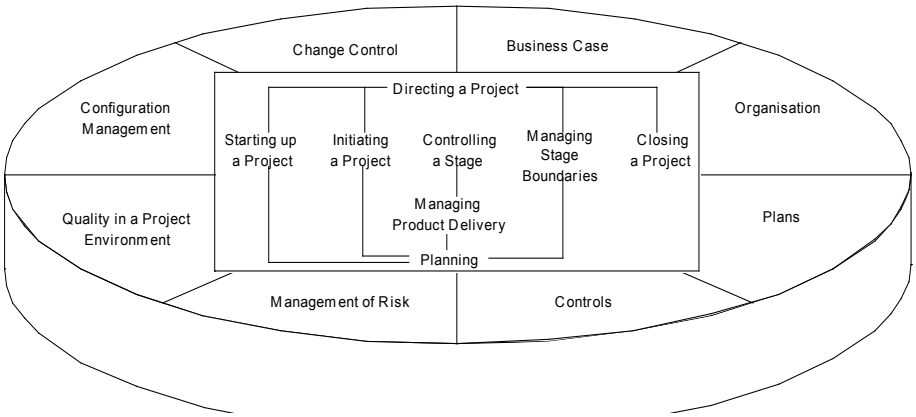
PRINCE is a structured method for achieving effective project management that has evolved in the UK. It was first established in 1989 by the UK Central

Computer and Telecommunications Agency as a standard to be used for all government IT projects, and was subsequently developed as an approach to project management for all projects. Since 1996 it has been a standard requirement that UK public sector projects are run using this version of the approach, PRINCE2.

Key features of the PRINCE2 approach include: 1) a clear business case, which sets out the aims of the project; 2) a defined and measurable set of "products" or results, together with the activities to achieve them; 3) defined resources linked to activities; and 4) an organisational structure, with defined responsibilities to manage the project (UK Office of Government Commerce) (Figure 1).

Typically, these features are captured in a set of project documents against which aims and progress are monitored, risks identified and managed, and changes to aims or activities controlled. The set of documents includes a project initiation document (PID), risk register, issues log, project plan and statement of success criteria.

Figure 1.
The Main Components of the PRINCE2 Approach.



The PRINCE2 approach is not intended to cover all aspects of management for every project, and the techniques and tools may vary according to the type of project and organisation carrying it out. Some aspects of project management are well covered by other well-proven methods, including people management techniques, generic planning approaches (e.g., Gantt charts, critical path analysis) and methods for controlling budgets. PRINCE2 is a coherent set of project management concepts and processes that provides a minimum set of requirements for a properly run project. But the approach fully recognises that each project may vary substantially, and that the particular approach to effective project management will require tailoring of the overall method.

PRINCE2 requires the production of a summary reporting document to a steering group and a related set of supporting documents and processes. The set of documents that were considered most appropriate for use in the MDP case included the following:

1. *A Project Initiation Document (PID)* — to summarise in one place the aims of the project, an outline project plan for all activities and deliverables by all parties, resources and budgets, key project dependencies (including critical external dependencies, e.g., supply of the gel and ethics committee approvals), reporting processes and governance structure, risks, and change control procedures.

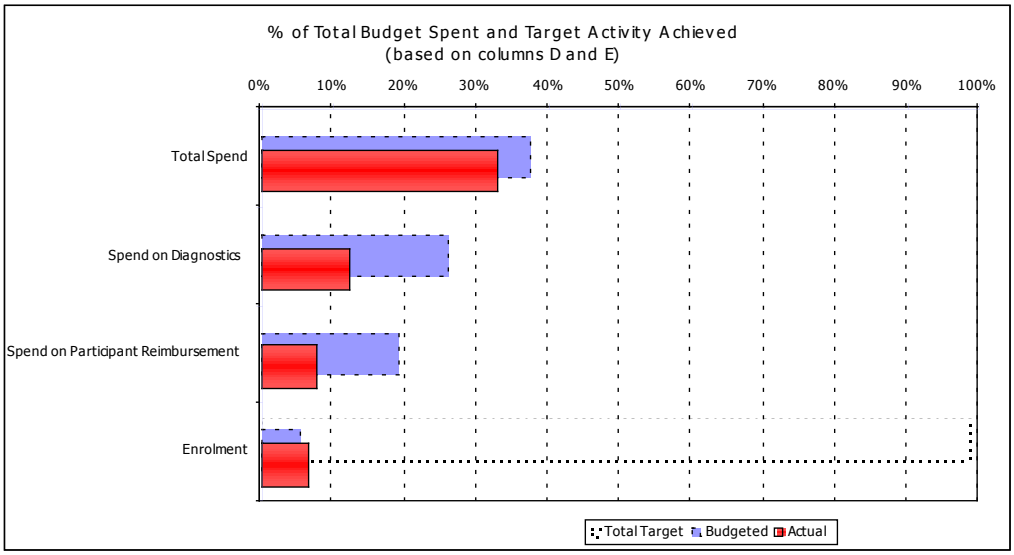
2. *Detailed Project Plan* — a consolidated overall plan of key deliverables, milestones and timescales.

3. *Financial Controls and Reporting Procedures* - these include financial profiles that link budgets and expenditures to activities, as well as the associated monitoring and corrective action procedures. In the MDP case the approach that was already being taken was modified to provide clearer reporting on progress with the trials (e.g., recruiting trial participants at the trial sites), and matching this progress against proportion of budget used. Financial spreadsheets were adapted to produce automatically graphical summaries for use by the project team and in reporting to DFID (Figure 2).

4. *Risk Register* – the majority of risks in the MDP case were already being anticipated and recorded by the trial management team, but not easily communicated to DFID. This document collated this information according to the groups of activities. Probability and severity of risks were also noted so that priorities could be determined. A "traffic light" warning system was employed to readily prioritise any risks.

5. *Issues Log* – to record risks that have become reality and identify what is being done to address them and by whom.

Figure 2.
Activity and Expenditure Data.



As the PRINCE2 approach was being applied to a project that had already started, it was decided not to create the PID (as the relevant documentation already existed, albeit not in one single document). Emphasis was therefore placed on modifying the approach to financial monitoring and reporting, and on identifying and reporting risks and issues.

Costs: The MDP Case

In the MDP case an existing approach to project management was modified. The information required was already being collected and, to a large extent, all of the project management functions implied by PRINCE2 were being implemented. However, these were not organised in a way that lent itself readily to linking progress and

planning of expenditures to activities, or to reporting in a transparent way that could be easily communicated to the funder in a standard format.

Table 1 summarises the costs associated with modifying the existing project management approach for MDP.

Table 1

Indicative Costs to Modify Project Office Documents and Processes on MDP

Activity	USD
Review of modifications to project office documents	15,000
• Review current project office documents against PRINCE2 standard	
• Discussions with PI, MRC Clinical Trials Unit (CTU)	
• Note to PI, MRC recommending changes to documents	
• Note to steering committee and DFID on recommended changes	
Implementation of changes to project office documents	20,000
• Note on current process for financial reporting and recommendation on changes	
• Production of worked example of modified quarterly financial reports (linking expenditures to activities)	
• Preparation of outline overall project plan	
• Adjustments to MRC CTU financial reporting spreadsheets to automate production of quarterly reports	
• Modifications to clinical site financial reporting templates and automation of data transfer to CTU reports	
Additional time for project office to implement changes ("one-off costs" only)	40,000
Total additional cost (USD)	**75,000**

It is likely that these costs would have been lower had a PRINCE2 (or similar) approach been adopted at the outset. But this is with the benefit of hindsight, and it must be recognised that even for the funder there was limited familiarity with this approach and hence an iterative process of learning and familiarisation.

Benefits: The MDP Case

The benefits of adopting the PRINCE2 approach in the MDP case are summarised in Table 2. Some of these are prospective, as the trial is still in progress and some of the modifications have yet to be fully implemented.

Although these benefits are qualitative (we do not attempt to put a financial measure against them), we believe the most important of these will result from more effective project management and from the enhanced relationship with the funding body rather than from quantifiable cost savings.

Nevertheless, one of the consequences of streamlining the quarterly reports to the steering committee and funder (DFID) has been that the time required to produce these reports has been reduced.

Table 2

Benefits to MDP from Modified Project Management

•	Improved understanding of the trial process at the funding body (DFID) and confidence in financial management
•	Ongoing savings in time for team members through standardisation of site reporting and automatic flagging of variances (for monitoring) between actual and forecast/budgeted expenditures
•	Improvements to project management effectiveness through explicit linking of activities and expenditure (objective measures aiding process of making future revisions to budgets)
•	Improvements in risk management from modifications to the risk register, and linking of the risk register to the high level reports
•	Ongoing savings in team project management time from streamlining and automating financial reports

Wider Benefits

In the MDP case, a primary reason for reviewing the project office documents was the request from DFID to improve the link between expenditure and activities in high level reporting. As the modifications to the reports were explored, wider benefits to the project managers and the team as a whole from the proposed modifications became apparent.

Our view is that there are substantial potential benefits for funding bodies, project managers, and research teams as a whole if project management is recognised as an explicit cost item at the project proposal stage and project management approaches are then adopted at the outset of a project.

Table 3 suggests where the main benefits might arise. The list of benefits reflects to a large extent what has already been shown in MDP. We also add potential benefits to the research team itself.

Table 3

Wider Benefits of Project Management in Research

Funder	Researchers	Research Managers
• Provides assurance of value for money through: • Clear reports of progress and plans for the next period. • Clear governance structure for decision making and for assignment of responsibilities. • Improving confidence that expenditure is well managed (i.e. tied to activities – milestones and deliverables). • Improving confidence that any risks to milestones or deliverables will be mitigated.	• Improves research team chances of winning research funds. • Aids knowledge transfer between team members (standard reporting and data accessibility). • Reduces time and risk in conveying knowledge between team members. • Potentially influences scientific outcomes by providing objective criteria for targeting efforts/ avoiding or managing risks.	• Improves management of relationship with funders. • Clarifies the plan, roles and responsibilities – reduces ambiguity in the project management task. • Assists with budgetary control (e.g. requires academics to engage more closely with the link between activities and resources). • Provides audit trail.

Wider Costs

While the ratios are not rigid, a common rule of thumb in management consulting is that project management costs represent on average 3% of total fees. Typically a full-time project manager is required on projects of £3m and over per year. In construction projects a common expectation is that project management will require 1.5% - 3% of the capital costs, but much depends on size and complexity and on which functions are included in project management.

As in the MDP case, it can be expected that cost will be lower if a coherent approach is built in from the beginning (from the proposal stage).

loaded on projects. Once the PID and project documents are set up, their maintenance by team members who understand the process is relatively economical. Properly administered, they also save administrative time on other tasks.

Clearly, in assessing costs adjustments, one needs to account for: (a) Scope – what will be included in project management, e.g., which of the PRINCE2 documents and processes are considered appropriate in each case; (b) Geographical spread of sites (consultant or client) and number of different parties involved (entities/team size); (c) Number of key decision points envisaged (need to take stock of progress and adjust plan); (d) Number of different disciplines (or work-streams) involved in the project; and (e) Size and duration of the project

Conclusion

The use of PRINCE2 to help manage MDP and use it to report back to DFID was fairly novel for all concerned — scientists, clinicians, and administrators alike. Indeed, Ove Arup and Partners Ltd. was commissioned to work with the team to develop the tools and techniques needed. The approach adopted gave a transparent

and robust tool for managing risks and budgets that enabled DFID to readily review a number of key performance indicators relevant to the trial and thereby obtain assurance about programme management and trial progress.

The tools and terminology were alien to the majority of those involved and therefore required overcoming a steep learning curve. It was also resource-intensive for a number of key staff as changes were made to the existing approach. Familiarising the consultants on clinical trial methodologies, on MDP itself and how the new tools should be scoped, developed, and managed required a significant amount of time from key MDP staff members. This was essential to download structure and intelligence to ensure the tools were accurate and *fit for purpose*. It is doubly essential, therefore, that tools and templates provide obvious efficiencies in the medium to long term.

It is important that techniques and tools of this kind are seen as adding value in terms of oversight and scrutiny rather than becoming an additional bureaucratic burden, particularly for the researchers. Whether this achievement can always be proven is a moot point. The mandates of Good Clinical Practice (GCP), FDA and other authorities require that data collection and storage, trial management, and processes per se must be of the highest quality. Project management, however, is less well defined - the majority of researchers, quite rightly, need to be convinced of the merit and benefit of incorporating these tools in order to accept the costs and resource implications of doing so. We suspect, however, that as the number, size, and complexity of research projects continue to increase, the need for formal project management will become more critical. It is likely that as research managers, we will be required to undertake the necessary training to support and work closely with our academic colleagues.

Reference

UK Office of Government Commerce. (Third edition Crown copyright 2002, Twelfth Impression 2005). *Managing successful projects with PRINCE2*.

Customer-Supplier Roles and Relationships in the Management of Research Projects

Dr. Ian M. Carter
Director of Research
Research and Business Services
University of Liverpool
Foresight Building
3 Brownlow Street
Liverpool
L69 3GL
UK
+44 151 794 8723
+44 151 794 8728 (fax)
i.carter@liv.ac.uk

Author's Note

This article derives its inspiration from a conversation between the author (when he was at the University of Glasgow) and staff at the then UK Office of Science and Technology about how Government approaches the commissioning of research. The matrix derived from that conversation has subsequently been used to help understand and tease out quality and process issues.

Abstract

Recognising the existence of customer-supplier roles and relationships in the performance of research can lead to an improvement in the management, and hence delivery, of research. Research, especially university-based research, is often managed with a light touch, with the researchers operating independently, and neither their institution nor their funder intervening to a great extent. Whilst this has significant advantages, the explicit understanding and execution of specific roles will enhance the research performance for both those undertaking research and those using its results. This paper presents a simple matrix to help explore the customer-supplier relationship, and to identify some key activities of each during different stages of the research process. Three stages are identified, relating to the commissioning and winning of funding, undertaking the research, and reporting and using the results. Each of these provides a focus for a set of roles, which might be the responsibility of different individuals or organisations. The role of the research administrator in this model is also explored, to show how it is an integral part.

Key Words: Research management, customer-supplier relationships

Introduction

Undertaking research involves a range of activities: generating the idea for the research, refining it and identifying the relevant hypotheses and questions; developing the method; generating the necessary funding; undertaking the studies to test the hypotheses and answer the questions; recording and reporting the results; and making use of the results in both specific and broader contexts. All of this involves a number of roles and responsibilities, including those of a customer-supplier nature. In some cases, the customer-supplier relationship is clearer (e.g. contract research) than in others (e.g.

grant-funded and institutionally-funded research). In institutionally-funded research, and in some types of externally grant-funded work, the institution may be acting as both customer and supplier (e.g. where the idea for the content of the research comes from the researcher themselves). This paper explores these roles with the aid of a simple matrix, and aims to show how performance can be improved with only a little additional conscious effort.

A reflection on customer-supplier relationships does not mean that one is operating a commercial model, or that it reduces the effectiveness of the research process, or academic freedom to investigate and express. Being well-organised, and understanding and responding to the person or organisation that is paying for the research, can only have beneficial effects in terms of making a case, winning funding and producing interesting results. Indeed, in the vast majority of academic applications for funding, those making the decisions are other academics. This does not reduce the need to understand what those other academics will be looking for, and what they believe to be a good outcome.

There are a number of other issues about customer-supplier relationships, in terms of the fundamental role of research support functions, and their provision of service to their customers, typically taken to be their institutional academic community. Even in this context, the recognition of the alternative customer bases of the institution and the external funder are important to recognise, in the knowledge that they require a different service from that of the academic researcher. A later section of this paper discusses the role of the research administrator in the customer-supplier interaction.

Whilst recognising the sensitivities that might exist about the terminology, the terms customer and supplier are used in this paper to reflect the roles of individuals or organisations in being the recipients or providers of research, respectively, and not in other, potentially more pejorative, ways.

The Customer-Supplier Research Matrix

Table 1 presents a simple matrix of customer and supplier roles during a three stage research process. The stages represent the major phases of determining what research is to be done and who is to do it, undertaking the research, and using the results. The relevant tasks, processes, activities and decisions do not, of course, fall neatly into the six boxes, but the broad distinctions are sufficient to support the discussion of the different roles undertaking the stages.

Table 1

The Customer-Supplier Research Matrix

Stage	Customer	Supplier
1	Commissioning	Winning the Business
2	Monitoring Progress	Doing the Research
3	Using the Results	Reporting the Results

Stage 1

The commissioning of research will take different forms, typically dependent on the type of funder. A company or government department might commission a piece of contract research to meet a specific need, relating to their strategic objectives. A Research Council or Federal research

funder[1], on the other hand, may make a call for proposals in a broad area, with less prescription of what should be delivered, or may have an open call for "responsive mode" applications in their subject area[2]. In between these two is investigator-led contract research, in which the researcher provides the hypothesis. The activity of commissioning is therefore different.

Contract Research

Funders at the contractual end of the spectrum would tend to determine the hypothesis and research question that they wish to have answered, and in trying to win the business, the supplier will try to show that they have the capability, capacity and track record to do so, as well as demonstrating value for money. A variation on this may be that the customer will define the issue to be addressed, with the expectation that the supplier will be able to define the research hypothesis. The nature of contract research varies, but it is often focused on problem-solving, rather than blue skies knowledge generation, and hence the commissioning process may be more constrained.

Suppliers will be best placed to respond, and hence to aid the customer's business, if they have an understanding of the needs of the customer, including the uses to which the research results will be put, so that they can demonstrate a good match with and understanding of the customer's underlying objectives. Submitting a standard grant proposal to a call for tenders[3] is not likely to be successful. In some cases, suppliers will have to be on an agreed/accredited list of suppliers.

An extension of contract research is service provision: the use of existing knowledge to the benefit of the customer, for payment, without the generation of new knowledge (i.e., the activity does not meet the Frascati definition of research (HEFCE, 1995)). In this type of activity, a standard purchaser – supplier relationship is more likely to apply, whereas research relationships will tend to have more dialogue and iterative participation between the parties.

Grant Research

A large proportion (and in some universities the vast majority) of research is closer to the grant-funded end of the spectrum, in which the details of the hypothesis, questions, method, etc. are determined by the academic researcher, to be evaluated by the funder on the quality of the research. In this case, the commissioner of the research, and hence one of the customers, is the researcher him- or herself, along with the institution. Many, if not most, institutions require grant applications to be approved by a researcher's head of department and/or Dean, plus institutional authority. Doing so is a form of commissioning process: "Yes, this project fits with the institutional/faculty/departmental strategy." This is becoming a more conscious process than it has in the past, although it is unlikely that the Head of Department and the Dean, let alone the researcher, is thinking of themselves as a "customer." Perhaps they should. This is already relatively common in the context of the resources required for the projects,

[1] The author is writing from a UK perspective, in which the Research Councils are the UK Government's research agencies, akin to the US National Science Foundation and National Institutes of Health, whilst individual Government departments commission specific research either directly or through a tendering process. References to Federal throughout the paper therefore relate to U.S. Federal agencies.

[2] Responsive Mode refers to a mechanism used by a funder in which proposals may be submitted at any time, or against specified deadlines, within a general area of interest, as opposed to Managed or Directed Mode, in which the funder defines more precisely the required research topics.

[3] A Call for Tenders is the formal contractual process used to elicit offers against a specification of work, and is used for a significant proportion of Government department-funded research

where the department head or Dean is being asked to confirm that there is space available, technical support, and so on. It is starting to become more explicit, as more countries move to or consider a full economic cost basis for their research (HEFCE, 2005). A consequence is that the researcher needs to show more explicitly why the research is worth supporting. Although this makes sound management sense, there will be arguments that this sort of approach is a restriction of academic freedom. Understanding that there is a form of customer-supplier relationship within the institution (as well as what is the true, legal nature of academic freedom (SURPC, 1997)) can help us to work through these issues.

This shift of focus of the responsibility for defining the research is interesting and important. It underlies the nature of academic freedom – to be able to ask questions – and is relevant to the increased emphasis on universities undertaking more research with industry, on a contractual basis; i.e. is it as reasonable in a research contract to modify the hypothesis as the work progresses as it might be in a research grant? The relationship between customer and supplier in terms of the work to be done is much more tightly bound in a research contract situation than in a research grant. Although this could be considered as an issue for Stage 2, it merits attention at this stage, as the freedom for manoeuvre will be determined by the agreement reached during Stage 1.

Some customers may be happy for divergence from the original goals to occur. However, they are likely to want to know, and to be part of the decisions to allow redirection and replanning. Understanding and enabling this partnership is important, and the means of doing so need to be addressed at the start, rather than half-way through, when the need arises.

In terms of winning the business, the grant process requires the supplier to understand the customer's needs, too. It will often be the case that certain areas or techniques are favoured or even in fashion. Understanding what has been funded recently can help. Equally, being in a position to influence (appropriately!) the interests, policies, objectives, and targets of the funder can be beneficial. This takes multiple streams of activity, including institutional interactions with the funder at senior levels, involvement of researchers on the funder's committees, and interactions of the individual researcher with the funder's staff, to talk through specific proposals. Those researchers who are more actively involved in the wider research community (e.g., reviewing proposals and publications, being members of decision-making committees) tend to have better success rates because they understand their subject and its funding environment; i.e., they understand their customer (which particularly includes their peer community) (Viner, Powell, & Green, 2004).

The role of the university's research support office (or equivalent) will also vary, depending upon the customer, and also on the researcher(s) involved. A support office should be researching the market needs, whether that is Government or Federal funders' objective areas, or the commercial market for research outputs or products. Both markets, but particularly the commercial market, require the ability to understand the institution's own expertise and capability, and how to package the range of options to best effect.

Stage 2

Having won the research grant or contract funding, the researcher then needs to get on and do the research. In a significant number of contexts, this is all that happens in this stage: the customer (internal or external) may have little contact and no involvement in the

progress of the research. This may or may not be reasonable, depending on the scope and timescale of the project. Longer-term grants will often require annual or intermediate progress reports, and some may involve a mid-stage review, to confirm continuance. Contracts will often require regular reporting or monitoring, which can come as a bit of a shock to a researcher more used to grant or Federal funding.

There are particular challenges at this stage. From the supplier's/researcher's position, maintaining contact with the customer and making regular reports can be highly valuable. Not only does it help to meet any specific reporting requirements, it can also help to give the customer confidence in the researcher, hence possibly allow some flexibility in the current work, as well as strengthening the researcher's position for extension or follow-on work. If this sounds as though it's only relevant to contractual situations, consider for a moment the position of a researcher running a Research Council or Federally-funded project. The funder will be keen to hear of successful progress, so that they can use that information in their own processes of seeking and allocating funds between programmes, and in demonstrating beneficial research outputs and outcomes to their own paymasters. Equally, the researcher providing progress reports to his or her department/faculty will help to disseminate the research results, and help to demonstrate their competence up their management line.

For the customer, active engagement with the research can help to ensure that the desired objectives are met, and importantly that the subsequent transfer of the results to their target is achieved more successfully. The customer will need to be careful to balance their involvement and need for reports, to be sure that such activities do not become detrimental to the research itself or be perceived to bias or influence the outcomes. However, maintaining a suitable oversight may enable the customer to make use of key results without having to wait until the formal completion of the work and its final report. This can also apply where the researcher is the customer, and may take the form of patenting and/or publishing results during the course of the work. Thus, in both these cases, elements of Stage 3 are taking place whilst the research is on-going during Stage 2.

Stage 3

Once the research is complete, the researcher will have to report the results. This may be a formality, or the payment for the work may rest on the quality and suitability of the report or other research product. In the institutional context, we might consider how much attention we pay to this, to ensure that all possible outputs are identified. For example, do we ensure final reports are of a suitable quality, make explicit links between outputs and the work that produced them, and maximise publicity for the findings? The customer, having received the results, should ensure that they answer the original questions, and act accordingly – depending on what their objectives were for the research. However, they should also look for tangential or secondary uses for the results: for example, could they be used by someone else in the organisation. This is especially relevant to grant-funded research in which one of the customers is the researcher's own institution: as well as other researchers potentially using the results, they should inform or feed directly into the institution's research-based teaching. Results may be used, directly or in modified form, to count for the knowledge transfer metrics against which many of us are now measured.[4] Similarly, whilst the results (hopefully)

[4] The UK uses metrics of knowledge transfer activity to demonstrate levels of activity and by implication the socio-economic effects. Some of these metrics are used directly in allocation of core Government funding to universities to support knowledge transfer: e.g. the Higher Education Innovation Fund in England, and the Knowledge Transfer Grant in Scotland.

answer the original questions, they may prompt additional issues to explore, or the methodology used might be applicable to another problem area. This discussion is also relevant to Government-funded research: the findings in one Department's research may be usable by another Department, which will require transparency of the activities and good communication links, for example via the departmental Chief Scientific Advisors.[5]

All of these comments apply equally where the institution or the researcher is the customer: Where does this lead next? Can the methodology be extended? Can it be applied elsewhere (e.g. on a different topic, or the same topic for a different customer)? Should this area of research still be a focus? Answering these questions will be part of the process of commissioning the next piece of research, and may happen explicitly or implicitly. Within a university, aside from further research, the results could be relevant for development into an exploitable technique or product, or creation of a Continuing Professional Development course, as well as becoming incorporated into mainstream learning and teaching.

Expanding the Matrix

This description of the research process, and the perspectives of both customer and supplier, necessarily suggests a linearity that does not generally exist. Stages 1, 2 and 3 overlap, and blur into each other, both for the single piece of research, and between different pieces of research. This makes understanding the roles even more important: not providing reports to the customer might lead to the supplier missing a second piece of work that the customer intends to commission; not being aware of the supplier's capacity constraints may lead to the customer missing a critical opportunity for their research to be done, with competitive / market implications. For an institution, being aware of the range of research being undertaken for a specific customer is necessary so that issues (such as slippage) can be headed off before they become crises, and new opportunities are identified and pursued (especially those in which several different researchers/groups are needed).

The original matrix can be expanded, as in Table 2, to include a number of activities that can be associated with each role and stage. As already observed, the appropriate agent to fulfil each role might vary between projects. Thus an organisation or individual needs to understand when it or they should fulfil a particular role, and hence is responsible for certain activities. The actions within the roles might vary depending on whether it is an internal or external customer. This can cause issues within an institution, such as a researcher negotiating contractual details rather than an authorised institutional official, or an administrator pursuing a commercialisation route that does not fit with the researcher's plans for the work.

The Role of Research Administrators in Customer-Supplier Relationships

The discussion so far has tended to concentrate on the academic researchers and their role in these relationships, and particularly noting that they might be their own customer. A couple of observations have been made about research administrative support staff, and it is worth some more thought on this area.

Aside from the support role, in helping researchers to apply for, win, and operate research and related activities, in which the administrator is providing a service to the researchers, support staff are also crucial

[5] Many UK Government Departments have a Chief Scientific Advisor; they interact under the auspices of the Government's Chief Scientific Advisor, who is the head of the Office of Government Science.

Table 2

The Expanded Customer-Supplier Research Matrix

Stage	Customer	Supplier
1	**Commissioning** • Define objectives, targets, and real needs of the research. • Understand suppliers (capability and capacity).	**Winning the Business** • Understand customer and their objectives. • Interact formally and informally at all levels with customer to understand and influence. • Know own (individual, group, institution) capabilities and capacity. • Understand the brief; pre-qualify. • Apply/tender/propose work to meet objectives.
2	**Monitoring Progress** • Keep watching brief. • Provide assistance where appropriate. • Look for further opportunities.	**Doing the Research** • Report regularly, to self, internally and to external customers. • Check customer is happy with progress. • Identify protectable IP • Look for "spin-off", other opportunities.
3	**Using the Results** • Read the final report! • Use the results, against original objectives. • Look for other uses of results. • Consider follow-on research/other research. • Exploit the results.	**Reporting the Results** • Produce final report – ensure it meets the customer's objectives. • Follow up to check it is OK, enquire about or suggest follow-on. • Publish the results (if permitted)

to the wider customer-supplier relationship that is being discussed in this paper. The administrator, whether centrally or locally-based, can have a role in understanding the external opportunities and market for their researchers' skills, might be responsible for elements of market analysis and promotion, and may be significantly involved in preparing the proposal for funding. All of these need attention to the customer requirements of the research. In some cases, the administrator will have a more established relationship with the funder than the researcher does, which can be used to good effect. Equally, the administrator may understand the institution's own workings better, and hence enable their researchers to have their proposals approved and enhance their internal profile.

We are now seeing more opportunities for key account relationships, in which a range of research and related activities are provided for a customer (typically a larger organisation, but can be both public and private sector); e.g. research projects, studentships, placements, consultancy, secondments, and training. Managing the relationship across these activities becomes necessary, with a level of complexity in most universities because they are supported by different parts of the administration (as well as probably being delivered by different parts of the academic structure, to reflect the skills and subject mix). The role of the research administrator can then be to help to form internal consortia, construct packages of products, and act as the bridge to the customer.

This change in approach may appear antagonistic to some researchers, and hence the administrator will also need to provide reassurance, for example about the researcher's freedom to undertake research. Research administrators can thus take active roles within the customer-supplier relationship, as well as supporting their researchers in fulfilling their roles.

Conclusions

The customer-supplier relationship is simple, but is also very accessible, and helps us to understand the roles in the commissioning and delivery of research, roles that may not have been particularly well explored in the past. In the context of governmental pressures for universities to assume responsibility for contributing a greater, even significant, part in the future economy (HM Treasury, 2004), there will be more need for the explicit management of customer-supplier relationships. This will be best achieved where there is a balance between the researcher's freedom to explore an issue or hypothesis and sufficient communication to ensure that the customer can be reassured about progress and outcomes. Customer-supplier relationships may currently be most often considered in the context of a contractual relationship with an external organisation, and hence possibly are already being managed appropriately. The benefits for a research organisation may therefore be in considering the internal customer-supplier interactions, and those involved in grant-funded research work. Much of what has been presented is intuitive; however, a more conscious approach could bring benefits to the individual researcher and to their institution.

Those who perform best will fulfil their own responsibilities, but will also be aware of others' responsibilities and support them where appropriate. Some individuals and organisations are already doing this. However, many of us may not be, and hence have opportunity for improvement. That begins by asking a critical question: Do you really know *your* customers and suppliers?

References

HEFCE (1995). Generic research: Method and data collection. Circular Letter 10/95, Annex B. http://www.hefce.ac.uk/pubs/hefce/1995/c10_95.htm

HEFCE (2005). Transparent approach to costing. http://www.jcpsg/guidance/about.htm

HM Treasury (2004). *10-year science and innovation framework*. http://www.hm-treasury.gov.uk./spending_review/spend_sr04/associated_documents/spending_sr04_science.cfm

SURPC (1997). Academic freedom and research. In Scottish Universities Research Policy Consortium *University research in Scotland: Developing a policy framework*. (pp. 91-98).

Viner, N., Powell, P., & Green, R. (2004). Institutionalised biases in the award of research grants: A preliminary analysis revisiting the principle of accumulative advantage. *Research Policy, 33,* 443-454.

Implementing Ethics Policies in Developing Countries: Ploughing On Parched Ground?

Professor Isaac N. Mazonde
Office of Research and Development
University of Botswana
Corner Nyerere / Notwane Road
Gaborone, Botswana
mazondei@mopipi.ub.bw

Dr. José Jackson-Malete
Deputy Director
Office of Research and Development
149 Centre for Continuing Education Building
P.O. Box UB 00708
University of Botswana
Gaborone, Botswana

Jeremy Sugarman, M.D., M.P.H., M.A.
Harvey M. Meyerhoff Professor of Bioethics and Medicine
Phoebe R. Berman Bioethics Institute
Johns Hopkins University
Hampton House 351
624 N. Broadway
Baltimore, Maryland 21205
USA

Authors' Note

The ideas for this paper originated from experiences gathered during the implementation of the Ethics Policy at the University of Botswana beginning in May 2005, and the deliberations of an international ethics conference held in Durban, South Africa in October 2006. The ideas were further developed from discussions during the Southern African Research Innovation and Management Association (SARIMA) conference held in Pretoria, South Africa, in May 2006.

Abstract

It is globally expected that universities will ensure that policies guiding researchers' conduct are in place and adhered to. This expectation is not waived in developing countries. Successful implementation of an ethics policy is facilitated by an appropriate national regulatory framework on which to base the argument for compliance. However, it is possible to implement such policies even when a regulatory framework is absent. The University of Botswana implemented a program to increase awareness of research ethics and to manage allegations of research misconduct through a needs assessment and seminars on the Responsible Conduct of Research (RCR). This paper describes this problem, and the success of the program initiated to address it. This program serves as a model for other research institutions in the developing world that may encounter similar challenges.

Introduction

Research integrity is a global concern. When research lacks integrity, it destroys public trust in the academic and scientific community (The National Academies Press, 2002). While this issue is important for all research institutions, it becomes increasingly complex in the setting of internationally collaborative research, in which local standards vary despite considerable global consensus regarding many aspects of research integrity and ethics.

International interest in research ethics became pronounced following World War II (Deyhle, Hess & LeCompte, 1992). This interest resulted from the inhumane treatment of human beings by Nazi physicians (Crigger, 1992). Subsequently, numerous bodies offered standards to help ensure the ethical conduct of research (CIOMS; Declaration of Helsinki). While there are some differences among these policies, most support the prospective review of research and informed consent.

In addition, every profession is governed by implicit or explicit standards of competence and conduct (Bayles, 1988). These standards help to ensure that professionals perform as expected and that the profession itself maintains quality and integrity. Accordingly, institutions are concerned with both the review and the responsible conduct of research. Because allegations of misconduct tend to be unique rather than routine at most institutions around the globe, few have extensive experience in responding to allegations. The uniqueness of allegations of misconduct makes it difficult for an institution to develop expertise in conducting inquiries and investigations (Rhoades, 2000; Lock, 1995; **Husemeyer**, 1995). However, a research misconduct allegation has the potential for a high impact, both on the individuals involved and the institution (Rhoades, 2000).

Much of the recently published literature concerning research ethics, integrity, and compliance comes from Northern and Western nations. Nevertheless, internationally collaborative research has become more commonplace in locations that may have fewer financial resources to develop ethics and compliance programs. Yet constructing such programs is possible. In this paper we discuss some of the difficulties inherent to setting up these programs in the developing world and describe one program that may serve as a model.

Difficulties with setting up ethics structures in developing countries

Perlman (2005) maintains that, in the United States, reliance on regulations to enforce ethics requirements has resulted in a focus on compliance with requirements rather than the ethical principles that underpin them (National Commission, 1979). Despite this shortcoming, the U.S. approach helps to ensure that vulnerable subjects are protected and that their rights, safety and welfare take priority over the interests of science.

The situation in many developing countries is very different due to a lack of national legislation that would form the required umbrella for ethics policies. In Botswana, for example, there is no national legislation on ethics. In particular, although the country has for years depended upon South Africa for specialized medical services, there is no tissue act to regulate the movement of human tissues across national borders, nor to oversee their disposal once laboratory procedures are completed. The Ministry of Health is the only ministry with an active ethics body. Its institutional review board (IRB) ensures adherence to standard international ethics. The lack of a national legislative framework is not unique to Botswana, but common across the sub-Saharan region.

This situation – like ploughing on parched ground — makes it very difficult for an academic institution to formulate and effectively enforce an ethics policy. More importantly, this explains in part why so many university faculty members and students lack awareness of the responsible conduct of research. It is not always clear whether faculty members flout the rules for responsible ethical conduct deliberately or out of ignorance. Although the scale of academic misconduct by staff at the University of Botswana (UB) is not well documented, cases involving both students and staff have occurred (Moahi et al., 2005). Some of these cases have involved both intellectual and financial misconduct and are usually handled confidentially within the university. Some cases, however, some cases have also reached the public media, putting the university's integrity at stake (Odubeng, 2004).

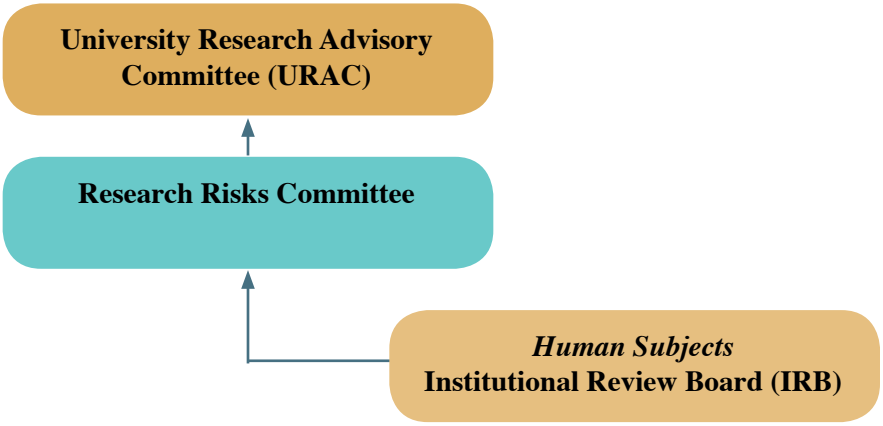
University of Botswana Ethics Policy

The objective of the ethics policy at the UB is to ensure that research is conducted according to internationally recognized ethical standards. Further, the implementation of the ethics policy represents another step toward handling of cases of academic misconduct and helping the university achieve its vision as a leading academic centre of excellence in Africa and the world.

The ethics policy at UB was approved in 2004. The Director of the Office of Research and Development (ORD) implements the policy through the Research Risks Committee (RRC). The RRC and its associated committees, including the IRB, the Animal Use and Care Committee (AUCC) and the Chemicals and other Hazardous Materials Committee (CHMC), were established in April 2005. The ORD Director is therefore responsible for ensuring that all research at UB follows both the ethical principles that have been set by the university and the laws and regulations governing research in Botswana. The Director also is responsible for fostering a culture of respect for research integrity; for ensuring the education of the ethics committees, researchers and staff on the ethical conduct of research; and for monitoring UB's ethics program.

Figure 1.

Reporting Structure for UB Human Subjects Institutional Review Board



The organization and administration of research ethics is demonstrated in Figure 1, which illustrates the relationship between the URAC, the RRC, and the IRB.

The University Research Advisory Committee (URAC), established in November 2002, advises the ORD on implementation of policy. The URAC consists of the Deans of each Faculty, the Director and Deputy Director of the ORD, the Dean of the School of Graduate Studies, the Faculty Research Committee Chairpersons, one person appointed by the Deputy Vice-Chancellor (Academic Affairs) to represent support staff, and the Manager of Special Projects from the Office of Financial Planning and Control.

The RRC has two primary roles:

1. To provide guidance in research ethics to the UB community, including, questions about misconduct (falsification, plagiarism, or misrepresentation of data), the level of contribution that warrants inclusion as an author on a publication, or ownership of a research idea. The RRC promotes awareness and compliance with the UB Policy on Ethics and Ethical Conduct of Research through periodic release of information to staff and students.

2. To review and make recommendations about all research proposed by UB staff or students. This responsibility is delegated to the three committees for which the RRC has oversight: the AUCC, the CHMC, and the IRB.

The UB Institutional Review Board for Protection of Human Subjects

The UB IRB is responsible for review of all human subject research activities consistent with U.S. federal regulations (Protection of Human Subjects, 2005). These broader definitions are critical to protecting the human subjects with whom UB investigators interact or about whom they obtain private information. When there is a question about whether an activity constitutes human subject research, the UB requires "a qualified person or persons other than the investigator or research team" to verify that the activity requires IRB review (Protection of Human Subjects).

IRB review is also extended to student research activities. In some courses, students collect data by using professional research methods, even though the work is not expected to contribute to generalizable knowledge. Because some methods involve human subjects, and in some instances place these subjects at risk, student research projects are reviewed and approved prior to initiation to assure that the rights and welfare of human subjects are protected.

To direct its operations, the UB IRB has established guidelines used by staff and students in both courses and research, and it has the authority to require adherence to these practices. Deviation from these standards is usually reported to the Director of ORD, who then takes further action as recommended by the RRC. The IRB also reviews all research protocols of staff and students in which human subjects are used. The committee is authorized to communicate approval and disapproval actions to those submitting the proposal, and is required to report all review outcomes to the RRC.

The IRB consists of 12 members appointed by the Director, ORD. Membership includes knowledgeable individuals from the local community, the Government, and UB. Additional individuals with special expertise may from time to time be designated as ad hoc members to assist the IRB. The committee is chaired by a member of the UB staff.

The IRB review process requires researchers to submit 12 copies each of the entire academic proposal, the completed UB application for Approval of Human Research, instructions to participants, the consent form, any questionnaires (translated as appropriate), and the curriculum vitae of the Principal Investigator(s).

The review process of the IRB consists of:

1. Discussion of any policy issues, conflict of interest or procedural matters.

2. Review of protocols.

   a. The IRB will establish and publicize to UB staff and students deadlines for submission of research projects for review.

   b. Each protocol is assigned to a member of the IRB for review. When additional expertise is required, the protocol may be assigned to an ad hoc member for review and presentation to the IRB.

   c. Review criteria are provided to the researcher and to the reviewer. A short, formal review with written comments is completed by the member to whom the review is assigned (see 2 b above) before the meeting, and will form the basis of the discussion during the meeting. Researchers may be asked to provide clarification or additional information to assist the deliberations of the IRB.

   d. The IRB acts on each research project it receives, and advises the researcher of the outcome. No research may be started until a research permit has been issued by the Ministry of Health.

   e. Some researchers have the habit of commencing research work before IRB approval is given. In view of that, the IRB will not accept requests for approval of research that is ongoing or completed and has not had prior approval.

The IRB is scheduled to meet at least quarterly, but may meet monthly if the protocols received for review call for that.

The IRB chair reports all board actions to the RRC, and communicates with the Chair of the RRC when conflicts of interest arise that affect the rights and welfare of participants. Conflicts may exist among IRB members and consultants, investigators, students, sponsors or administrators. Any case of research misconduct or serious or continuing noncompliance with regulations pertaining to research and/or university policy may be reported to the RRC as an allegation of misconduct by the IRB chair, any member of the IRB, human subjects or any other individual.

UB IRB pilot review of proposals.
The UB IRB began reviewing university research in November 2005 on a pilot basis for those researchers who received funding from URAC. The outcome of this first round of reviews is shown in Table 1. None of the proposals was deemed exempt from review; 20% qualified for expedited review and 80% were assigned to the full board. None of the proposals was approved on the first review, as all had both methodological and ethical issues that needed to be addressed. Sixty percent were approved on the second review; the IRB requested that two researchers attend a meeting to discuss and clarify their proposals. Four proposals are still pending.

Table 1

Statistics on Review of Research Proposals

Status of proposals	Number
Proposals received for review	10
Proposals exempted from review	0
Proposals for expedited review	2
Proposals for full board review	8
Proposals approved at 1st review	0
Proposals approved at 2nd review	6
Researchers invited to IRB meeting	2
Proposals pending	4

Among the challenges in operating the board are the following:

1. Time constraints – committee members often have limited time to dedicate to the IRB because of conflicting activities involved in teaching, research and other committee memberships. As a result, members who attend often do not form a quorum, which makes decision making difficult.

2. Administrative constraints – No staff member is dedicated solely to administration of the IRB. This responsibility was added to a staff member's already full work load. However, it soon became obvious that IRB administration itself is a full-time job, in terms of coordinating meetings, the protocol reviews, organizing paperwork, and communicating with researchers (even for this pilot project, which did not include all the research conducted by the University).

3. Ethical versus methodological review – while it is widely known that the IRB may review both the research and ethical considerations of a protocol, most of the methodological issues should be addressed by the committee allocating research funding. However, many questions regarding methodology were left to the IRB to clarify.

4. Monitoring of researcher compliance – continuous checking of projects to ensure that researchers are adhering to the regulations is impossible at this time, given the staffing situation. This problem is expected to become even more difficult once this pilot phase is over and review of all university research begins.

To alleviate some of these problems and improve operations, the UB IRB has made specific suggestions to the ORD. First, it has requested a dedicated staff member, trained in research ethics, to serve as the IRB Administrator. This will provide for smoother operation of the IRB and faster communication to researchers. The IRB also recommended that the committee allocating research funding conduct more thorough reviews to ensure that proposals approved for funding have sound methodologies that do not require further exhaustive review by the IRB. This has been addressed by revising the tools that the peer review panel uses to allocate funding. A more thorough methodological review may also alleviate the time commitment of IRB members, who could concentrate on ethical, rather than methodological, issues.

Responsible Conduct of Research Seminar Series

Researchers in many institutions globally must receive instruction in nine core areas of responsible conduct of research (RCR) to be eligible to receive public funding for research (ORI, 2005). These core areas and other relevant topics have been adopted by UB into a seminar series available throughout the academic year and targeted at increasing the awareness of researchers on issues related to RCR. The series focuses on aspects of planning, conducting and reviewing and reporting on research, as follows: Planning research: (a) research involving human subjects, (b) research involving animals, (c) research involving the use of chemicals, (d) management of research funds, and (e) conflict of interest and commitment; Conducting research: (a) data acquisition, management, sharing, and ownership, (b) mentor/trainee responsibilities; Reviewing and reporting research: (a) research collaboration, (b) publication practices and responsible authorship, and (c) peer review.

An RCR training needs survey was administered to 300 academic staff members simultaneously with the seminar series to assess the educational needs at UB in RCR and the handling of allegations of scientific misconduct. Responses from 115 individuals were received, which represented a 38% response rate. It was designed to identify who should receive training, what instructional materials were needed, the topics the training should address, useful teaching resources, formats and methods, and strategies for increasing awareness about RCR.

A majority of the respondents considered RCR training as useful primarily for graduate and undergraduate students, researchers, research assistants, training and development officers, Ethics Committee members, and financial project officers. A total of 82.1% of respondents considered seminars an appropriate format for delivering instructions in RCR; 59.5% cited a manual on RCR; 52.4% preferred Web-Based Modules and only 11.9% preferred audio tapes.

The topics recommended for RCR training programs are shown in Table 2. The main topics of interest for researchers were collaborative research and misconduct in research (78.6% in each case), authorship/publication (75%) and intellectual property (71.4%). For graduate students, the topics recommended were education in research misconduct (76.2%), research design (69%), intellectual property (63.1%) and scientific record keeping (61.9). For undergraduate students, misconduct in research (60.7%) was identified as a crucial topic, as well as research design (52.4%). The majority of researchers felt that more adequate instructional materials were needed for selected RCR topics. The primary topics included research design (71.1%), penalties for misconduct in research (57.9%), lab safety (53.5%), and misconduct in research (51.8%).

Table 2

RCR Topics that Training should Address and that Require Additional Instructional Materials

RCR Topics	Responses for research group (%)			Researcher responses for instructional materials (%)
	Researchers	*Grad students*	*Undergrad students*	
Research Design	69.0	69.0	52.4	71.1
Scientific record keeping	54.8	61.9	46.4	39.5
Human/Animal subjects	48.8	46.4	39.3	46.5
Lab safety	28.6	38.1	28.6	53.5
Funds management	61.9	41.7	27.4	35.1
Mentoring	63.1	28.6	20.2	34.2
Collaborative research	78.6	44.0	26.2	32.5
Authorship/Publication	75.0	59.5	32.1	37.7
Authorship of student work	56.0	53.0	46.4	22.8
Peer review	63.1	44.0	28.6	43.0
Intellectual property	71.4	63.1	45.2	48.2
Conflicts of interest and conflicts of commitment	59.5	36.9	21.4	36.0
Misconduct in research	78.6	76.2	60.7	51.8
Penalties for misconduct in research	60.7	60.7	46.4	57.9
Institutional policies on research misconduct	53.6	48.8	34.5	25.4
Whistle blower and / or reporting misconduct	53.6	48.8	34.5	3.5

Administrators at UB were also asked about the management of issues related to research misconduct. The Deputy Vice Chancellor of Academic Affairs, all Deans and Heads of Departments were identified as the administrators most needing training in this area (Table 3). However, it must be noted that some respondents suggested that all researchers needed training in the management of allegations of misconduct.

The specific topics in terms of the management of allegations are shown in Table 4. Among the topics for administrators, policy requirements (62.5%), reporting to the UB community and the public media (62.5%), restoring reputation (58.3%), and treatment of respondents and whistle blowers (54.2%) were the primary ones identified. For research integrity officials, important topics included developing investigation plans (54.2%), handling evidence and sequestering of data (54.2%), interviewing (50%), and responding to retaliation complaints (50.0%). For researchers, the important topics were conflicts of interest (50%), maintaining confidentiality (48.5%) and developing investigation plans (45.8%). In terms of the format of the training program,

Table 3

Type of Staff to Receive Training on Managing Allegations

Staff	*Positive response (%)*
University Administrators	
Vice Chancellor (VC)	58.3
Deputy VC Academic Affairs	70.8
Deputy VC Financial Affairs	45.8
Deputy VC Students' Affairs	45.8
Deans	87.5
Heads of Departments	83.3
Directors of Centers	66.7
Public Affairs staff	44.1
Research Integrity Officials	
Chair, research risks committee	54.2
Members, Research Risks Committees	45.8
Members, Research Ethics Committees	66.7
Researchers	
Academic staff	79.2
Others	
Faculty Research and Publication Committee	58.3
Others	25.0

the majority (69.6%) felt that the most effective format was within a leadership training program or an Administrators Annual Retreat organized jointly by ORD and the Centre for Academic Development (CAD). Over half (52.6%) also felt that RCR training should be included in the induction program for Heads of Departments.

The majority of administrators felt it was important that feedback on allegations of misconduct at UB be provided to university staff, but less so to the press and the general public. The data showed that 90.9% wanted feedback on publicly reported cases while 69.6% wanted such cases to be publicized by the press. Administrators also suggested that guidelines, examples of best practices and case studies, as well as a dedicated research integrity officer, were the most appropriate resources for the management of allegations of misconduct.

Ploughing On Parched Ground?

This paper highlights the limitations within which developing country institutions such as the University of Botswana work. While the ethical principles outlined in the Belmont Report seem to have broad reach, an emphasis on compliance rather than ethics may lead to untenable approaches in the developing world. Throughout Southern Africa, problems with ascertaining compliance may in part be due to the lack of a national framework to support relevant policies relating to ethics and associated legislation such as intellectual property and data management. Notwithstanding the shortage of overarching ethics legislation, however, the University of Botswana has

Table 4

Topics Training should Address

Topics	*Positive response (%)*			
	UB Admin	*RI Officials*	*Researchers*	*Others*
Policy requirements	62.5	37.5	37.5	8.3
Maintaining confidentiality	45.8	41.7	48.5	8.3
Protection against conflicts of interests	33.3	37.5	50.0	4.2
Assuring appropriate expertise	29.2	29.2	25.0	4.2
Treatment of respondents & whistle blowers	54.2	45.8	25.0	4.2
Developing investigation plans	29.2	54.2	45.8	4.2
Handling evidence and sequestering of data	25.0	54.2	33.3	8.3
Requirement of proof	37.5	45.8	20.8	4.2
Interviewing	20.8	50.0	41.7	8.3
Preparing reports	16.7	41.7	25.0	8.3
Responding to retaliation complaints	41.7	50.0	25.0	8.3
Restoring reputation	58.3	37.5	16.7	8.3
Reporting to UB community	62.5	29.2	25.0	8.3
Reporting to public media	62.5	20.8	12.5	8.3
Departmental/Faculty Appeals	25.0	29.2	29.2	12.5
Research Risks Appeals	29.2	41.7	25.0	4.2
Committee hearings	20.8	45.8	16.7	8.3
Others	4.2	4.2	4.2	4.2

been able to achieve a culture of responsible ethical conduct among its researchers. While a lack of support from above and complimentarity with others addressing the same problems may be likened to ploughing on parched ground, the success of the University of Botswana can be replicated by institutions in similar settings.

References

Bayles, M. (1988). *Professional ethics* (2nd ed.). Belmont, CA: Wadsworth.

Crigger, B. (1992). Twenty years after: the legacy of the Tuskegee syphilis study. *Hastings Center Report,* 22(6), 29.

Deyhle, D.L., Hess, G.A., Jr., & LeCompte, M.D. (1992). Approaching ethical issues for qualitative researches in education. In M.D. LeCompte, W.L. Millroy, & J. Preissle (Eds.), *The handbook of qualitative research in education* (pp. 597-643). Toronto: Academic Press Inc.

Doberneck, D. (Ed.). (2004, Spring). Research Mentoring. *Michigan State University Research Integrity Newsletter,* 7(4). Retrieved February 14, 2006 from www.msu.edu/user/gradschl/all/ris04.pdf

Husemeyer, R.P. (1995). Handling scientific fraud. *British Medical Journal, 311,* 261-262.

Lock, S. (1995). Lessons from the Pearce affair: Handling scientific fraud. *British Medical Journal, 310,* 1547-8.

Moahi, K., Becker, C, Lee, M., Kuruba, G., Jackson-Malete, J., Masupo, S., et al. (2005). *Report of the task group on academic dishonesty in the University of Botswana*. University of Botswana.

National Commission for the Protection of Human Subjects in Biomedical and Behavioral Research (1979). *The Belmont Report: Ethical principles and guidelines for the protection of human subjects*. Washington, DC: Department of Health, Education and Welfare.

Odubeng, M. (2004, February). UB exam papers disappear. *Mmegi Online Newspaper,* 21(24). Retrieved February 16, 2006 from http://www.mmegi.bw/2004/February/Monday16/10584761891225.html

Office of Research Integrity. (2005, October). *Teaching tools for responsible conduct of research*. Presented at the annual meeting of the Society of Research Administrators International, Milwaukee, WI.

Perlman, D. (2005). Putting the ethics back into research ethics: A process for ethical reflection for human research protection. *The Journal of Research Administration*, 37(1), 13-22.

Protection of Human Research Subjects, 45 C.F.R. § 46 (2005).

Rhoades, L.J. (2000).The American experience: Lessons learned. *Science and Engineering Ethics,* 6(1), 95-107.

The National Academies Press. (2002). Integrity in scientific research: *Creating an environment that promotes responsible conduct*. Retrieved February 16, 2006 from http://www.nap.edu/catalog/10430.html

Administration of an Innovative Program of International Cooperation: Success Across the Pond

Vincent S. Gallicchio, Ph.D., Dp (hon)
Associate Vice President of Research
Professor, Biological Sciences and Public Health Sciences
Research Division
Clemson University
301A Brackett Hall
Clemson, SC 29634-5701, USA
864-656-1643 (office); 864-656-0881 (fax)
vsgall@CLEMSON.EDU

Author's Note

The author acknowledges Ms. Lynn Kunkle, Grants Administrator, and Ms. Emily Land, Office of Sponsored Programs, Clemson University for their thoughtful and helpful discussions. This project was supported in part by grants from the U.S. Department of Education; Funding for the Improvement of Postsecondary Education (FIPSE), Washington, D.C. (P116J050001), awarded to Clemson University, Clemson, SC and from the European Union (2003-4033-CPTUSA), Brussels, Belgium.

Abstract

The world continues to change rapidly and globalization is fostering common social, economic, and political agreements among countries. Agreements by governments have created opportunities to enhance educational and research endeavors that, by design, will remove barriers that previously have limited the flow of students, educators, researchers, and professionals across borders. Global access has opened the door to mobility in higher education, encouraging the development of educational standards and mutual mechanisms of recognition. Three years ago an eight-institution consortium comprised of four American and four European institutions of higher learning came together in a partnership to provide opportunities for students and faculty to share the educational and research experience internationally. A partnership of this magnitude was constructed despite barriers that were both administrative and cultural in origin. Through a positive approach, a framework for a transatlantic program of educational and research cooperation was developed. A significant level of mutual cooperation effectively solved the administrative hurdles initially encountered in the realm of research. We believe a model has been created that fosters the development of international programs to benefit faculty, students, and research administrators as they work to effectively interact in the global environment.

Key Words: Research administration, international education, study abroad

Introduction

The world is rapidly changing, and globalization is helping to establish common social, economic, and political agreements between countries, as evidenced by the 1993 Maastricht Agreement that created the European Union (EU) and the 1994 North American Free Trade Agreement between the United States, Canada, and Mexico. These agreements provide the context and rationale for government involvement in enhancing educational opportunities and removing barriers that limit the flow of students, educators, professionals, practices, and projects across borders. Having opened the doors to North

American and European mobility in higher education, this increased global activity has encouraged the development of common education standards and mechanisms for mutual recognition, and liberated processes by which professionals are permitted to practice. For example, the educational ministries within the EU have mandated through the Bologna Declaration that by 2010 all educational curricula, course syllabi, textbooks, and related materials must be identical within the EU countries. This means that whether an institution is educating an architect or a zoologist, the educational methodology will be identical to its counterpart institutions' programs throughout the EU. Therefore, this Declaration has been designed not just to lower barriers, but to remove them entirely.

These barriers also exist in the U. S. They are generated by responding to the criteria for specific academic curricula that in many cases are imposed, or at the very least influenced by accreditation agencies, certification bodies, ministries of education and health, and licensure laws, because education and training can differ from state to state and country to country. These barriers will create unique challenges for higher education in the U.S. as our graduates try to stay competitive in the global economy. Thus, global mobility of students has now been recognized as an important component of the educational experience to help address concerns related to differences — not just to the academics in a particular curriculum, but more importantly to help facilitate a better understanding in culture among the peoples of these countries.

An integrated effort to help promote the joint collaboration between higher educational institutions within the United States and the EU has been in place for several years based upon a treaty of mutual cooperation. The origin of this cooperation in education and training dates from the Transatlantic Declaration on EU-U.S. relations adopted in November 1990. In 1993, a two-year exploratory phase of cooperation was launched, and the experience gained provided the basis for a formal EU-U.S. Cooperation Agreement signed in June 1993. Since that time a total of 107 transatlantic consortia have been funded involving 726 European and U.S. institutions of higher education and vocational training. More than 4,000 U.S. and EU students have completed portions of their programs of study abroad within these consortia projects.

To enhance the cultural awareness of students while removing their academic, research and practice differences across borders, three years ago an international consortium comprised of four American and four European institutions of higher learning united to establish a mutual student exchange program (Table 1).

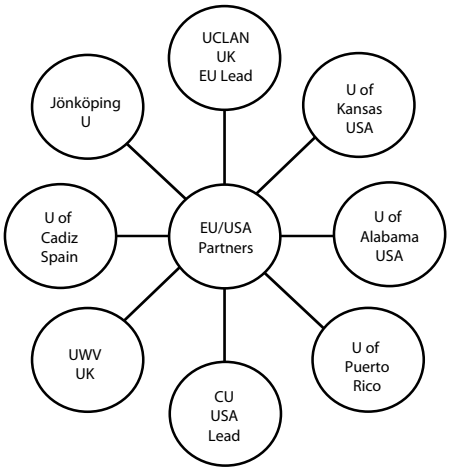
Table 1

Institutions Comprising the Transatlantic Health Science Consortium

United States of America	European Union
Clemson University, U.S., Lead	University of Central Lancashire, UK, Lead
University of Alabama, Birmingham	University of Wolverhampton, UK
University of Kansas	Jönköping University, Sweden
University of Puerto Rico	University of Cadiz, Spain

The integration of the eight institutions is diagrammed in Figure 1.The Consortium agreed to target biomedical science as the initial academic area of focus, with interest in other areas to be identified following the matriculation of the consortium program. This partnership has now been extended to programs in behavioral science and business.

Figure 1.
Illustration of the Transatlantic Model for Clinical/Biomedical Sciences.



From the perspective of the research administration office, a program of this scope focusing on international cooperation creates unique challenges. Obligatory components such as memoranda of understanding (MOU) and sub-contractual agreements are potential hurdles that must be overcome to provide the necessary instruments for the ultimate success of the project. There is also the potential challenge of overcoming language barriers. This article describes those challenges and how they were addressed to best serve both the individual institutions and, importantly, the students who participated in the international study abroad exchange program.

Importance of International Education

These are challenging times in which we live. We have embarked on the 21st century like no other time in human history. Life changes almost daily, as reading the newspaper or listening to the evening network news can attest. A list of these changes, by no means complete, gives us an idea of their scope and effect on our daily lives. Changes to our economy, education, environment, livelihood, health, natural and non-renewable resources, nations and people are profound in their impact on how we will live in the future.

We in higher education are not immune to these changes. In representing institutions of higher learning, we have been governed by the simple fact that our role and responsibility is to educate students. This remains the basic core value in our mission statements; however, what has changed and will continue to change is the climate and environment within which our students will enter the job force of the future. The challenge of higher education today and tomorrow is to make sure that our graduates leave our institutions not just with the necessary knowledge in their respective disciplines required to become successful, but more importantly, the necessary skills to live and work in a global economy.

To achieve this combined success, educational institutions will need to change the way they meet their mission. To address this challenge, we must ensure that our curricula become internationalized, thus providing our students all the necessary skills to become as marketable as possible as they seek to enter the international work force.

How can this be accomplished? We must internationalize the curriculum to emphasize the importance of the study abroad experience for our students. This valuable experience allows students to learn a portion of their area of study while sitting next to their host country classmates in the foreign site. This allows our students to hone the skills necessary to survive in the international setting, whether survival is defined as simply being able to communicate or, more complexly, to sustain a livelihood. Importantly, these interactions allow the visiting student the opportunity to learn more about the history, culture, and language of the host country.

International education and the opportunity to study abroad allow students to broaden their horizons and think beyond their own individual area of influence. For the institution, internationally focused education and curriculum bring added value to the overall experience (Gallicchio, 1993). We must provide the best education and training possible for our students if they are to become successful competitors in the global community. If we fail, we will have negatively impacted our graduates' ability to be the best possible adults.

International experience as part of an educational system is imperative – program by program — to the interest and commitment of participating institutions. To be successful, there must be adequate and effective communication among specific groups, all of which share a strong belief in blending the international education experience into their educational programs. Administrators, faculty and, most important of all, students are the essential components for success of any such program.

Focus on the Academics—Role of Research in International Education

Over the years, the role of research and scholarly activity has been a hallmark of American higher education, in many cases attracting foreign students to study in the U.S. However, in several areas of U.S. higher education, especially within the health professions, a focus on conducting research has not been emphasized. In several areas, specifically clinical laboratory and biomedical science, an increase in the performance of research by faculty over the last decades has gained significant importance (Covey & Burke, 1987; Bruhn, 1987). This increased effort arose in reaction to criticism that academic programs within the health professions have been deficient in their commitment to conduct scientific and scholarly activities. It also has been noted that those few programs conducting research or sponsored activity received little or no recognition. (Karni & Waller, 1999) It is essential in today's health care environment that health professions' faculty initiate and conduct research and scholarly activity. In addition to their mission of contributing to the improvement and delivery of health care, research and scholarly activity fulfills the responsibility of building the knowledge base of the individual academic disciplines (Syed, 1991). The criteria to evaluate colleges and schools of health professions have for too long highlighted the following deficiencies: (a) historically, members of health professions' faculty/staff have achieved academic ranks and tenure without the rigors of having to demonstrate scholarly productivity on a level with what is expected of faculty/staff members in other schools

and colleges on the same campus; (b) the majority of the faculty/staff within these units have a weak track-record of capturing external grant funding for research; and (c) the school or college does not have graduate programs. (Kraemer & Lyons, 1989; Waller, et al., 1988) The important points to emphasize in the performance of scholarly activity are research, graduate education, and the provision of research opportunities to faculty and students. Academic programs that incorporate international collaborations have been effective instruments in achieving research excellence (Gallicchio, Kirk & Birch, 1998).

Focus on Administrators

Leadership is the key role for administrators in programs incorporating international collaborations. Opportunities for the promotion of collaboration can be either interdisciplinary or inter-institutional. When the possibilities to develop programs of this nature are identified, it is critically important to have administrators in place who both support and believe in what is trying to be accomplished. Without the cooperation and advocacy of the appropriate administrators, more often than not, such projects become very difficult, if not impossible, to implement. It is particularly important for the appropriate administrators to view first-hand the international site, including the classrooms, laboratories, clinical facilities, and dormitory facilities where students will be housed. Administrators must also make sure programmatic areas of emphasis are within the overall institutional goals and objectives. In some cases this can be referred to as a strategic plan. Because administrators are required to sign off on documents essential to implementing study abroad programs, e.g., memoranda of understanding (MOU), having them in the loop as early as possible can avoid delays at best and rejection at worst when review of these programs becomes necessary.

Focus on Faculty

The importance of international opportunities for academic faculty and staff can be significant. International programs can provide faculty with access to students capable of conducting research, who would not otherwise have been available within the program, department, school, or college. . The faculty member also gains skills in the supervision of sponsored student research programs, skills they may not have had previously. This aspect of the program is important because it allows for the direct interaction of the faculty member in the supervision of students.

The criteria to evaluate health professions' faculty for too long have focused on the following issues: (a) historically, health professions' faculty have achieved academic ranks and tenure without having to demonstrate scholarly productivity on a level comparable with other university faculty; (b) the majority of health professions' faculty within these units historically had a weak track-record of capturing external grant funding for research; and (c) there existed a lack of graduate programs within the schools or colleges of health professions; therefore, a climate that fosters the development of researchers performed by researchers was absent. These issues have clearly re-defined the academic role of health professionals' faculty in today's academic environment that clearly demonstrates the performance of scholarly activity as defined by research, graduate education, and the provision of research opportunities to faculty and students. (Kraemer & Lyons, 1989; Waller, et al., 1988)

One method to increase research and scholarly collaborative activity is through the use of cooperative interactions between faculty from different schools or colleges. This collaboration can be regional, national

or international. Collaborative research incorporates the use and participation of multiple investigators, usually each with a defined role and purpose in the objectives of the project. An additional advantage of collaborative efforts is that they can be either interdisciplinary or multidisciplinary.

Focus on Students

The opportunities for students, whether undergraduate or graduate, to engage in generating scholarly activity in health professions have been limited or non-existent. An international consortium to promote the exchange of students in clinical laboratory and biomedical science was organized to provide educational opportunities to advance the knowledge base of participating students. This program afforded students the opportunity to both exchange ideas and become involved in educational partnerships and research collaborations (Hope-Kearns, Gallicchio & Ward-Cook, 2004).

The Role of the Research Administrator

The performance of sponsored research requires the cooperation of a team of skilled individuals. The obvious lead member of this team is the principal investigator (PI). Not so obvious are research administrators, who typically work behind the scenes, often hidden from the limelight. . Research administrators are responsible for reviewing and processing pre-award proposals, maintaining post-award research accounts, and overseeing various aspects of compliance (e.g., research involving the use of human subjects, animals, and biological or chemical hazardous agents).

Often collaborative projects among faculties of different institutions (whether they are focused or involved in research and/or education) are conducted under complex arrangements. When conducted under sponsored research, these collaborations are usually performed under sub-recipient agreements that require careful preparation and review by a skilled grant administrator. These agreements must cover the objectives of the project while following the sponsored agency and institutional guidelines.

The Transatlantic Health Science Consortium Experience

The Transatlantic Health Science Consortium (THSC) has succeeded by overcoming several initial obstacles that, if not resolved, would have made its implementation difficult if not impossible.

First, the MOU was an important document required by the sponsoring agency and the participating institutions. The MOU determined the exact conditions under which the program was to be conducted. It specified such terms as academic credit, accommodation/housing, tuition, and general rules pertaining to the conduct and performance of the international student enrolled in the host country institution. Each institutional grant researcher had input in the formation of the MOU, and the role of the grant administrator was critical.

The MOU also highlighted language differences among the collaborators. One of the EU partners, the University of Cadiz, mandated that the document be translated in Spanish. Another EU partner, Jönköping University, did not require a Swedish translation because all of its administration and faculty were fluent in English. In fact, Jönköping University's biomedical science curriculum is taught in English.

Second, the sub-recipient agreement served to describe the project in terms of funding and implementation. Each lead institution by definition of the sponsoring agency was the recipient of the total funding, respectively. However, in the absence of a sub-recipient agreement, the allocation of funds for each of the participating partner

institutions could not be provided. The research administrator was instrumental in ensuring the success of the project by incorporating specific institutional policy into these agreements.

Third, the project required a renewal sub-recipient agreement for each of the three years the grant was funded. Each year submission of a project scope list was required. This was a list provided by each of the project site institutions detailing what they planned to accomplish over the next 12 months and how their funding would accomplish these goals. Research administration viewed this list as mandatory; otherwise the sub-recipient agreement for that particular institution would not be validated for that year, resulting in a lack of funds.

Fourth, the project required an annual progress assessment, which also included a financial statement pertaining to the allocation of funding for the previous year and how this funding was spent. Research administration facilitated the process of collecting and validating this information to the sponsor's satisfaction.

In the final analysis, research administrators played a critical role in the overall grant process. In addition to providing the proper project oversight required by the sponsoring agency, they also ensured that institutional policies and procedures were followed during the performance of the project. As more of their time became devoted to compliance issues such as these, research administrators continued to serve as important members of the team.

The Future

The United States has long been engaged in an aggressive competition for international students. For years, international students came to the U.S. to be educated and to gain experience by making active contributions to their respected field of study. Many of the best and brightest international students who were once totally committed to study in the U.S. are now studying elsewhere or staying at home. This change has evolved in part since 9/11. Changes in policy mandated by the Departments of Education, Homeland Security, and State have altered the ability of international students and scholars to pursue the opportunity to study in the U.S. Although the circumstances that created these changes are understandable, the overall long-term consequences and eventual impact on the ability of the U.S. to maintain its leadership in many academic areas and research are now in jeopardy. A concerted effort must be made by both policy makers and educators to work together to re-establish the U.S. as the place for international students to be educated. In so doing, important contributions are made to American society as these students go on to become active members of the global community.

Thus, it will continue to be through education and research that we will be allowed to return to the forefront in providing opportunities for international students. The consortium described in this report is an example of a new strategy for international program development. The focus for the future pursues a more ambitious aim of implementing joint or dual transatlantic undergraduate degrees within a smaller consortium. This is based on the rationale that the growing pace of global interconnectedness in virtually all aspects of human life means our post-secondary institutions must rethink how best to prepare students for a lifetime of work in an international environment, i.e., "the world is getting flat" (Friedman, 2005). In doing so, the EU and U.S. governments intend to support collaborative projects that can

contribute to innovation and the acquisition of skills required for meeting the challenges of the global knowledge-based economy. Those most successful colleges and universities in the future will increasingly define themselves as truly international in terms of their educational activities and the demographic profile of their faculty and students. While the research community has to a larger extent embraced the global dimension, as reflected in broad and intensive international collaborative activity, the study and teaching dimensions of higher education still have to address this challenge in a truly international perspective. In the EU-U.S. context the next aim is to address this challenge by developing and testing a new and more integrated form of international education: transatlantic joint degrees. This innovative initiative will undoubtedly create new challenges for research administration in order to allow the colleges and universities that select this high ground to succeed.

References

Bruhn, J. G. (1987). The changing limits of professionalism in allied health. *Journal of Allied Health,* 16, 111-118.

Covey, P. C., & Burke, J. E. (1987). Research and the mission of schools in allied health. *Journal of Allied Health,* 16, 1-5.

Friedman, Thomas L. (2005). The world is flat — A brief history of the twenty-first century. New York: Farrar, Stratus and Giroux.

Gallicchio, V. S. (1993). Process development of an international cooperative exchange program for faculty and students in allied health emphasizing academic and research initiatives. *Journal of Allied Health,* 22, 439-445.

Gallicchio, V. S., Kirk, P., & Birch, N. J. (1998). Use of an international faculty/student exchange program as a process to establish and improve graduate education and research within an allied health discipline. *Journal of Allied Health,* 27, 31-34.

Hope-Kearns, E., Gallicchio, V. S., & Ward-Cook, K. (2004). International survey of program directors opens doors toward ASCP globalization: An innovative transatlantic student exchange program. *Laboratory Medicine,* 35, 466-469.

Karni, K. R., & Waller, K. V. (1999). Comparing CLS faculty and allied health deans and directors: Time spent in academic activities and perceptions of the research environment. *Clinical Laboratory Science,* 12(6), 332-335.

Kraemer, L. G., & Lyons, K. J. (1989). Research productivity of allied health faculty in academic health science centers. *Journal of Allied Health,* 18(4), 349-359.

Syed, H. (1991). Collaborative research. *Journal of Allied Health,* 20, 69-73.

Waller, K. V., Jordan, L., Gierhart, J., Brodnik, M. P., Schiller, M. R., Flanigan, et al. (1988). Research skills and the research environment: A needs assessment of allied health faculty. *Journal of Allied Health,* 17(2), 101-113.

Book Review:

Managing Scientists: Leadership Strategies in Scientific Research (2004)

Alice Sapienza, Wiley-Liss, Inc., 246 pp.

Frances Chandler, M.A., Ph.D. (cand.)
Associate Director
Office of Research Services
Brock University
St. Catharines, Ontario, Canada

Managing Scientists: Leadership Strategies in Scientific Research is the kind of book that researchers in all disciplines, not just the sciences, will want to read in their capacities as Principal Investigators (PIs), collaborators or team members. It is equally useful to research administrators charged with the responsibility of assisting scholars who may benefit from help in leading, managing, and collaborating with peers, students, post doctoral fellows, and bureaucrats. Alice Sapienza believes this second edition further illuminates those consequences that arise when PIs are unable to mediate, mentor, or manage their projects. Like others who write in her field, Sapienza notes that "poor leadership results almost invariably in poor productivity and a lack of creativity" (Preface, p. x), and that emerging theories, polices, and practices need to be easily accessed and implemented to ensure maximum output from the research project and its participants. She suggests that "the journey from occupying a managerial/leadership role to being an effective leader sometimes begins with a book" (Preface, p. x), and this book is one that she feels will provide researchers with context-specific examples of the joys and challenges of leading and managing in an academic milieu.

I am not a scientist, but in my capacity as a university administrator I offer assistance in managing scientific research projects. Over time I have come to understand that many of the challenges researchers face are not unique to their discipline. I also understand that, while they are cognizant of the latest scientific studies in their fields, they typically are not aware of emerging leadership literature. As a result, my role as an administrator involves apprising them of those theories, models, and practices that will have an impact on their work. This role is one that we, as research administrators, are called upon to assume in our capacities as managers, leaders, planners, counselors, conciliators, and compliance officers, so we need to be aware of these new and emerging theories and tools.

Alice Sapienza also supports this assertion, and as a professor of leadership, she is uniquely situated to study and appreciate the issues articulated to her by individuals who take part in scientific research. Over a three-year period she and a colleague conducted a study of scientists engaged in research; the results of her findings are published in this book. Encouraged by her reflections, new theories of management and leadership, and a renewed enthusiasm for the topic area, she has written a book that is an excellent resource for research administrators, PIs, and others engaged in scientific research.

What makes this book of interest to members of SRA is the author's unique perspective – one that is familiar to us. Sapienza knows that, based in a setting

where the main activity "occurs between the ears of scientists" (p.168), it is difficult to adapt management strategies from the private sector to academia, as there is a difference between a "discovery organization" and "development organization" (p.168-169) in regards to the expectations related to output.

She suggests that we need to be cognizant of the differing purposes of discovery and development organizations, as well as the project management language used in each. For example, there is a marked difference between the traditional definitions of project management and those used in discovery organizations. Words such as *develop, construct,* and *implement* are widely used in development organizations, while *explore* and *discover* (p. 168) are used in research settings. These differences need to be understood by research administrators who are disseminating information on new approaches to leadership and project management. We need to be selective as to what theories or models will be most useful to our cohort prior to addressing their questions and concerns about the management of their research projects.

Unfortunately, there is a lack of research on this differentiation that Sapienza writes about. This dearth of information is both what compelled her to conduct research on this topic and what has encouraged me to undertake doctoral studies in project management and leadership within a knowledge-based university environment.

We both know that discovery organizations are unique in their development and structure, but as an emerging scholar, I do not have the breadth of experience that Sapienza possesses. Therefore, I refer to her book, among others, when deciding on an approach I might suggest to researchers starting a new project or revamping an existing one.

The approaches I choose are based on what I read in journals and books such as this one, and what I hear from researchers when they "find themselves leading other scientists and technical personnel" (Preface, p. xi). I am particularly drawn to Sapienza's chapter on organizational structure, as it is beneficial to all of us in the business of supporting researchers as they design and create a practical and operational organization for their new or floundering projects. Chapter Nine is devoted to this discussion and the unique culture within which we develop these structures.

A chapter entitled *Being Different* refers to the cultural, ethnic, age, educational, and gender diversity found within collaborative research teams. Comprised of individuals from different disciplines and backgrounds, these team members need to sort out divergent views on appropriate methodologies, philosophical approaches, power, equality, role differentiation and the sharing of intellectual property rights.

These divergent viewpoints may also affect how a collaborative is managed. In Chapter Seven, Sapienza addresses the issue of project management and the important role it can play in developing creativity and respect among members. PIs need to think about designing a management structure and developing a leadership style that best meets the needs of the participants, while research administrators have an obligation to assist them by reading, deciphering, and retrofitting current theories to their unique environment.

This sentiment is echoed by Sapienza in Chapter Three, where she discusses the definition of motivation and theories related to it. She writes that, to be proficient at motivating employees, a fit must occur when balancing job demands, personal competencies, and organizational characteristics. Her diagram depicting three

intersecting circles provides the reader with a visual representation of how important it is to balance these three spheres to create an optimum environment for creativity and knowledge creation. She also notes that there are human and technical aspects within each circle that must be considered. For example, education, skills, and training are found within the technical aspects, while work, motivation needs and leadership style are considered human characteristics.

The latter is what Sapienza suggests is the most difficult, and I am sure that most of us in our roles as research administrators would agree, based on what we hear from researchers. In my capacity as an Associate Director of Research Services I cannot recall more than a handful of questions from faculty members regarding the research process, but in relation to human resource and management issues, the queries are numerous.

It is precisely for this reason that books such as this one are important for us to read, understand, and relay to our constituents. Easy to follow, it combines a how-to approach while interweaving context–specific, new and established theories on leadership and project management.

Divided into 10 chapters, *Managing Scientists: Leadership Strategies in Scientific Research* outlines issues related to effective communication, conflict resolution, assessment of the working culture, and leading change. It includes examples from within the research environment and results from the three-year research project that formed the basis for the book. It lists new understandings that the author has acquired as a result of her research, indicating the ongoing personal growth that she says is so important when managing or leading people.

She writes that we all need to understand ourselves, and in so doing, respectfully articulate our needs to ensure the achievement of personal and group goals. These skills are not innate, so it is imperative that we, as research administrators, are aware of the latest theories and tools that will assist researchers, then package the material and deliver it in a timely and accessible format to our target audience.

For example, contrary to what classical scholars believed, it is now widely held that the contingency model of leadership effectiveness is the best. Sapienza discusses this model in the fourth chapter by referring to Fred Fiedler's assertion that proficient leaders emerge only as a result of a good fit between leadership style and three other elements: 1) leader-member relations, 2) task structure, and 3) power position (p. 73). It is this model that she introduces as a basis for her discussion on the need to change one's leadership style to suit unstable environments and the ever-changing situations that emerge from within and outside of them.

She also suggests that we need to employ all the resources we have at our disposal when dealing with conflict, as well as individual, organizational, and power differences. For example, I rely on my skills as a social worker when acting as a mediator between researchers who may not agree on the direction of the research, my planning skills when assisting them with their management structure, and my teaching skills when relaying new information to them that I have learned as a result of my doctoral studies. I know that I need to keep abreast of the changes in my environment, so continue to read, study, and disseminate my knowledge to those I serve within my institution.

Sapienza's book has provided me with some excellent ideas about what researchers might find useful, and although her focus is on

a scientific lab setting, she outlines some excellent strategies that are transferable to researchers in other disciplines. At the very least, we should all read this book so that we can better understand that the challenges researchers articulate to us on regular basis are not specific to one individual, project, university, laboratory, or country, but are universal.

As the Society of Research Administrators International approaches its 40th anniversary and expands its reach to more locations than ever before, it behooves us to stay current, share our new and evolving insights with others, and maintain an active role in the research enterprise as well as its administration. This book will assist us in this endeavour.

Law Review:
Recent Developments in Research Law

J. Michael Slocum
Slocum & Boddie, PC
6225 Brandon Ave. Suite 310Springfield, VA 22150
(703) 451-9001, Fax: (703) 451-8557
jmichaelslocum@slocumboddie.com

Eric Guttag
Jagtiani + Guttag
Cincinnati, OH

J. Mark Waxman
Foley & Lardner
Boston, MA

Jill Williamson
Alston & Bird LLP
Washington, DC

Authors' Note

Over the past year there have been important developments in the law related to research and research administration. Some of these changes are outlined in this article, which was conceived and written by a group of attorneys with expertise in topics of particular importance to the research institution. Many of the issues addressed are related to intellectual property, but there are important developments in other areas of the law as well, including new and proposed changes to export regulations and exciting new developments in research collaborations. The authors would like to give a special thanks to Amanda Boddie, a summer intern at Slocum & Boddie, PC, and a new law student at the Catholic University of America in Washington, for her efforts to pull the various topics together and to assure some level of continuity and consistency in the language in this article.

An Overview of Export Law and Regulations

Current federal export laws control a wide range of technologies and some of the regulations outlined in them can have a substantial impact on research. These laws control the conditions under which certain information, technologies, and commodities can be transmitted overseas to anyone (including U.S. citizens) or to foreign nationals (even if in the U.S.), and some of these regulations will be outlined in this section.

Export Administration Regulations

The responsibility of the Bureau of Industry and Security (BIS) in the U.S. Department of Commerce is to apply and enforce the Export Administration Regulations (EAR) (15 CFR chapter VII, subchapter C). The EAR is responsible for regulating the export and re-export of numerous commercial items, including those that have dual-use applications, which means that they may be used in both the military and commercial realms. Other government agencies, such as the U.S. Department of State, regulate defense items.

A small percentage of U.S. exports and re-exports regulated by the EAR require a license from BIS. To obtain a license, information must be provided regarding the item that is being exported, its anticipated use, and the recipient and final destination of the item. There are 10 specific categories that require a license: nuclear materials; chemicals, microorganisms, toxins; materials processing; electronics; computers; telecommunications; lasers and sensors; avionics; marine; and propulsion systems (See §734.2(a) of the EAR for items that are subject to the EAR).

International Traffic in Arms Regulations
The U.S strictly regulates exports and re-exports of defense items and technologies to protect its national interests in peace and security. The Directorate of Defense Trade Controls (DDTC), Bureau of Political-Military Affairs, Department of State, in accordance with 22 U.S.C. 2778-2780 of the Arms Export Control Act (AECA) and the International Traffic in Arms Regulations (ITAR) (22 CFR Parts 120-130), is charged with controlling the export and temporary import of defense articles and defense services covered by the United States Munitions List (USML). (22 CFR § 121.1)

The purpose of ITAR is the control of arms sales to foreign parties to protect U.S. national security and to further U.S. foreign policies. The Core of the ITAR is the United States Munitions List (USML). Items included on this list are those that are deemed to have a military use or one that allows Americans in military situations to defend themselves by disarming or eliminating their adversaries. The ITAR governs license applications for exports dealing with matters related to defense trade compliance and enforcement, and also assumes responsibility for the creation of defense trade reports to Congress and the public (Defense Trade Function Overview, n.d.)

As one would expect, items such as weapons, chemical and biological agents, military vehicles, and equipment all have a military use according to ITAR. However, all satellites and related technology and data are now added to this list. Both the ITAR and the EAR are now subsuming control over applied research such as satellite technology, that was once considered to be of a non-military nature. In spite of a longstanding official policy that exempted *fundamental research* from the export regimes, these organizations have increasingly been expanding their jurisdictional reach to include items such as satellites (22 CFR § 121.1 Category VIII).

Office of Foreign Assets Control
The Office of Foreign Assets Control, or OFAC (2002 CFR Title 31, Volume 2 Chapter V), is part of the U.S. Department of Treasury and is the organization responsible for administering and enforcing economic and trade sanctions. OFAC has the authority to impose comprehensive or selective control over transactions between the U.S. and other countries and to freeze foreign assets. This role is mandated by American foreign policy related to national security concerns such as terrorism and the proliferation of weapons of mass destruction.

OFAC also has the power to provide general licenses authorizing the performance of certain categories of transactions and to provide restricted licenses on a case-by-case basis subject to specific conditions. These particular transactions, which OFAC is empowered to oversee, are referred to as *prohibited transactions* and may include trade or financial embargos between and among U.S. citizens and foreigners. Unless expressly authorized by OFAC or exempted by statute, prohibited transactions are to be adhered to by the parties involved. However, each program, such as the Anti-

Terrorism program and the Anti-Drug program, is based upon different foreign policy and national security goals so the prohibitions may differ. In some cases, a license is needed to undertake almost any transaction involving a citizen of a targeted country while in other cases only specified individuals or companies are subject to restriction or prohibition.

The National Policy on the Transfer of Scientific, Technical, and Engineering Information, NSDD 189

There has been a longstanding tension between the perceived need to protect national security through the control of technical information while at the same time providing an environment that allows for free and open scientific discourse to take place to advance scientific knowledge. This tension has been balanced through a carefully negotiated Fundamental Research Exclusion policy that allows published research that is already in the public domain to be excluded from licensing such as that overseen by OFAC. This exclusion applies only to disclosures in the U.S. at accredited institutions of higher learning and may be reversed if these institutions accept federal funding for projects that are subject to specific national security controls.

Bona-fide, U.S. citizens employed full time at American universities are allowed, under ITAR, to share unclassified technical data with foreign nationals who are also employees of American universities and who reside in America. This exemption may only be applied when the employee is not a national of an embargoed country and upon receipt of a signed agreement that disallows the sharing of information with other foreign nationals without prior government approval. There are limitations to this exemption however, as in the case of graduate or doctoral students who may not have full-time employee status or the foreign visa holder who is required to maintain a foreign residence.

The National Policy on the Transfer of Scientific, Technical, and Engineering Information, or NSDD 189, generally provides that products of fundamental research are to continue to be unrestricted. This policy, created under President Reagan in 1981 (NSDD 189, 1985), states that:

> *Fundamental research* in this sense is defined as the basic and applied research in science and engineering, the results of which ordinarily are published and shared broadly within the scientific community, as distinguished from proprietary research and from industrial development, design, production, and product utilization, the results of which ordinarily are restricted for proprietary or national security reasons.

For national security reasons, there may be instances when control of information is necessary and data that are generated during federally funded research in science, technology, and engineering at colleges, universities, and laboratories are subject to review. Various federal agencies use a form of classification to determine the level of control of this information. These agencies are responsible for: (a) determining whether classification is appropriate prior to the award of a research grant, contract, or cooperative agreement and, if so, controlling the research results through standard classification procedures; and (b) periodically reviewing all research grants, contracts, or cooperative agreements for potential classification. No restrictions may be placed upon the conduct or reporting of federally funded fundamental research that has not received national security classification, except as provided in applicable U.S. statutes.

The expansive definition of export continues to be a problem in research even with the exemption provided by NSDD 189. In situations where export controls stipulate that a license is required but no exemption is available, a license must be obtained before export-controlled items or information can be shared abroad or with foreign nationals participating in research on U.S. campuses. For example, restrictions exist for dissemination of information at conferences where unpublished research is to be presented and when assisting foreign collaborators with understanding how to use items in research (defense service) or transfers of research equipment abroad. Finally, no licenses at all are available for exports to embargoed countries and those countries designated as supporting terrorist activities (15 CFR chapter VII Part 764, Supplement 3; See also 15 CFR chapter VII Section 744.1(c)).

The NSDD 189 and other legislation such as the Bayh-Dole Act (PL 96-517, Patent and Trademark Act Amendments of 1980), have an impact on every area of research. For example, current export laws control a wide range of technologies including those created by researchers at educational institutions or by medical personnel. Most recently the Association of American Universities (AAU) has taken the lead in protecting principles outlined in NSDD 189. On October 16, 2006 the AAU commented on the newest draft of the proposed Department of Defense (DOD) rules concerning export controls as follows (DFARS Case, AAU comments, 2-3 2006):

> In terms of specific improvements, we are pleased that the new rule has been modified to eliminate overly prescriptive provisions that went far beyond existing Export Administration Regulations (EAR) and the International Traffic in Arms Regulations (ITAR). In particular, we are pleased that the proposed requirement for unique badging and segregated work areas for foreign nationals has been removed. We also appreciate that the new proposed rule addresses the concern raised by AAU about the "flow-down" of export-control contract clauses from commercial entities to university subcontractors. Finally, AAU appreciates that this new proposal more explicitly references National Security Decision Directive 189 (NSDD 189).
>
> AAU continues to maintain that DOD clauses pertaining to export controls should place the burden of export controls compliance on the contractor. DOD should avoid turning its contracting and program officers into export control compliance officers. The only instances in which contracting officers should be involved in export control determinations are when the research to be performed is not fundamental and when the information required to conduct the research, or the research results, are known at the outset to require security controls or classification.

Deemed Exports, Immigration Policy, and Universities

There are some key issues associated with the proposed rules on export from the so-called *deemed export* rules. Institutions of higher education have a responsibility to make certain that any and all research conducted under their sponsorship protects the national security of the U.S. and complies with export rules and regulations. However, with the current rules in place at universities, progression within the scientific community and the conduct of research can be seriously hindered. Stringent guidelines related to how researchers undertake

their work, has meant that the progress of collaborative science may be impeded.

The deemed export rule (See §734.2(b)(2)(ii) of the Export Administration Regulations) has been set in place to protect U.S, national security, and applies when "an export of technology or source code (except encryption source code) is deemed to take place when it is released to a foreign national within the United States" (Deemed Export FAQ's). Thus, under this rule, an export is considered to take place when covered information is disclosed to a non-citizen even though the disclosure happens inside the United States (persons with permanent resident status are often exempt from the restrictions). Universities and companies that have foreign nationals as students or employees must comply with these rules when access to controlled technology is granted to them. However, if a foreign national has been granted permanent residence, U.S. citizenship, or considered a *protected person,* he or she may be exempt from the deemed export rule.

The Department of Commerce Office of Inspector General (OIG) (The Inspector General Act of 1978, 5 U.S.C.A. Appendix 3) has expressed concerns over certain existing policies of the Export Administration Regulations (EAR). The OIG takes the position that a loophole exists in export licensing related to the current policy of using a person's country of residency, rather than citizenship, in determining whether an export license is required. The OIG outlined its concerns in a report to the Bureau of Industry and Security entitled *Deemed Export Controls May Not Stop the Transfer of Sensitive Technology to Foreign Nationals in the U.S.* (Final Inspection Report, 2004). This report suggested that foreign nationals, originally from a country of concern, could maintain residency in another country that would not require a license to obtain access to controlled information.

The initiatives posed by OIG could have a chilling effect on the research community. For example, an academic institution might be required to identify the country of origin of students, researchers, or others at the institution to determine whether they would need an export license to gain access to controlled information. The AAU (Revision and Clarification, 2005) made note of this concern by suggesting that "the reality is that the largest fraction of the best and brightest students that America's research universities attract comes from what the Department refers to as 'countries of concern,' especially China, India, Russia, Pakistan and Israel." Apprehension about export controls could lead to situations in which research is governed by these concerns rather than scientific expertise of a researcher when assigning certain projects or taking on new research ideas.

The concern regarding federal laws that has been expressed by the AAU relates to state law as well. As of April 2007, 50 state legislatures, and even some counties, had introduced over 1,200 bills and resolutions related to immigration. The Immigration and Compliance Act (06 SB529/AP, 2006), which went into effect in Georgia on July 1, 2007, is one such law. This law affects any entity that contracts or subcontracts with the state of Georgia, is a Georgia State entity, has any 1099 employees in Georgia, or provides state benefits to Georgians. Obviously this legislation encompasses most universities and many other research organizations. Some key provisions of the Act are included below:

1. Affected contractors and subcontractors with over 500 employees are required to register

and use BASIC, the federal electronic employment verification system, and submit an affidavit of compliance;

2. Affected contractors and subcontractors with 100 or more employees will have to register and use BASIC beginning July 2008;

3. All other affected contractors and subcontractors must register and use BASIC by July 2009;

4. All state entities will be required to use BASIC for all new hires;

5. State income tax deductions for business expenses related to employment of employees for whom the employer has not properly verified residency status, are disallowed; and

6. Tax for payments amounting to 6%, made via 1099, will be withheld if the recipient has not provided a valid taxpayer identification number (06 SB529/AP, 2006).

This new law is worth the attention of all universities and research organizations not just those physically located within the state of Georgia. It is not clear what the impact of the law will be outside of the state or even internationally but several provisions may result in unintended complications. For example, the Act has an impact on the salaries of both regular and *1099 employees* within the state (i.e., consultants, part-timers who are not on the regular payroll, and "independent contractors" who are providing personal services to the company or institution), regardless of where the employer is located (06 SB529/AP, 2006). Additionally, the Act applies to contractors and subcontractors providing services in Georgia, regardless of where they are located. Contractors and subcontractors located outside the U.S. are not eligible to use BASIC.

In addition to Georgia other states across the nation are continuing to take matters into their own hands when it comes to immigration policies. While Congress and the White House continue to have heated debates over immigration policies, more than 57 new statutes have been enacted in over 18 states including Oklahoma, Maryland, and Arkansas **(Prah, 2007).**

Oklahoma's new immigration law allows police to arrest illegal immigrants, restrict their benefits, and makes it against the law to harbor illegal immigrants. In addition, the new Oklahoma law requires companies to verify that new employees they hire are legal U.S. citizens (**Prah, 2007).** Following suit, Arkansas has enacted laws that bar any state agencies from working with companies hiring illegal immigrants **(Prah, 2007).**

However, not all new immigration laws are focused on barring and excluding illegal immigrants. Although Oklahoma is moving toward a tougher stance on immigration, in-state tuition and aid to students of illegal immigrants is still allowed, provided they begin the U.S. citizen process within one year of beginning their college education (**Prah, 2007).** Among Maryland's new policies are programs designed to persuade immigrants to learn English and encourage them to begin the process of becoming a U.S. citizen **(Prah, 2007).**

The export and immigration issues continue to be controversial and fluid. Any organizations that are comprised of foreign students, professors, or researchers, should remain alert to the potentially crippling effect of national security concerns on fundamental research.

Intellectual Property Issues and Patent Rights

Many cases in the past several years have clearly indicated that the impact of these laws is significant in relation to intellectual

property. In Madey v. Duke University (307 F.3d 1351, 2002 U.S. App. LEXIS 20823) (Fed. Cir., 2002) (Madey), for example, the Federal Circuit took a stand against the experimental use defense and several institutions have turned to the Supreme Court for help arguing that the effects of this decision against experimental use could set up harmful roadblocks to the progression of science. Some of these decisions are noted in this section.

The Experimental Use Defense to Patent Infringement: Madey v. Duke University
In *Madey v. Duke University*, the Court of Appeals for the Federal Circuit overturned the decision made by the District Court. Dr. Madey, former head of Duke's free electron laser (FEL) research lab, filed suit against Duke for patent infringement. Madey claimed that three pieces of equipment that were in Duke's FEL lab were covered by one or both of his patents and that Duke was unauthorized to use them.

In District Court, Duke University was granted a partial summary judgment (no trial was necessary) on the grounds of an experimental use defense. The District Court acknowledged that this defense applied to uses "solely for research, academic or experimental purposes" (Madey, at 1355). The District Court also recognized "the debate over the scope of the experimental use defense," but held that this defense was "viable for experimental non-profit purposes" (Madey, at 1355).

The Federal Circuit, however, viewed the experimental use defense as too broadly applied in this case holding that the research projects carried out by Duke "unmistakably further the institution's legitimate business objectives, including educating and enlightening students and faculty participating in these projects" (Madey, at 1362). As far as the Federal Circuit was concerned, the profit or non-profit status of Duke's research was irrelevant to whether the experimental use defense applied (Madey, at 1363).

The outcome of this trial could have damaging effects on the scientific community. Many academic and other research institutions have weighed in as the case goes to the Supreme Court for further appellate review, arguing that the effects of this decision against experimental use could establish almost insurmountable roadblocks to the progression of science. Now when research institutions want to further their research agendas they will be faced with additional costs due to delays caused by the time spent on researching patents or dealing with difficult patent holders.

While the Federal Circuit, after the Madey case, may have left the experimental use defense with little remaining value, universities and other non-profit research institutions are not without other viable options for immunizing their research from patent infringement. In fact, there are at least three potential safe harbors that universities and other non-profit research institutions can and should consider: (a) for state entities' immunity under the Eleventh Amendment; (b) immunity under the Hatch-Waxman Act; and (c) immunity under the federal contractor's defense of 28 U.S.C. §1498(a).

The Washington University v. Catalona et al.
In another case involving a university and a former employee, *The Washington University v. William J. Catalona, et al.* (U.S. App. LEXIS 14442 (8th Cir. Mo., June 20, 2007)), the court ruled in favor of the university. Unlike the *Madey* case, there was no dispute in *Catalona* involving patent rights or violations but the Court's ruling could have major implications for intellectual property ownership disputes.

In *Catalona,* Judge Stephen Limbaugh heard arguments regarding the ownership

of patient-donated biological samples. After the proceedings Judge Limbaugh ruled in favor of Washington University at Saint Louis (WU), granting it sole ownership of all biological samples donated for research purposes to its bio-repository. The Judge further ruled that the researchers and research participants (RPs) had no legal claims to ownership of any donated biological samples.

Dr. Catalona, a researcher and urologist, was employed by WU from July 1976 until February 2003 when he left WU to pursue a job at Northwestern University. Upon his departure from WU, Catalona mailed letters to those who had donated samples to the bio-repository at WU, asking them to authorize the release of their samples to him so he could continue his research at Northwestern. Six thousand donors signed and returned their release forms to Catalona. Nevertheless, WU refused to release the samples and filed suit to determine their ownership.

WU believed it owned the samples because they were donated as gifts to the university to use in research and maintained it was in exclusive ownership of the samples throughout the entire period of Catalona's employment. It entered into evidence forms that Catalona had signed that clearly stated WU was the owner of all biological samples donated for research purposes.

The basis of Catalona's argument was that no gift was made to WU. The defense asserted that because of *exculpatory* language (i.e., language that purported to excuse the university from liability) contained in the informed consent forms, no gift could have been made to WU. Dr. Catalona also argued that the RPs made donations with the intention that their samples be given to Catalona to further his research. Furthermore, Dr. Catalona's attorneys asserted that the RPs believed their right to remove themselves from the research study gave them the additional right to determine where and how their samples were to be used.

There were two cases used as guidance in Catalona: *Greenberg, et. al. v. Miami Children's Hospital Research Institute, Inc., et. al. (2003) and Moore v. The Regents of the University of California, et. al.* (1990).

In Greenberg, the plaintiffs argued they had property interest in their donated body tissue and genetic information, but the court declined to support this argument, noting that donations to research are made without any expectations of return of the body tissue and genetic samples. In *Moore,* a patient undergoing treatment for hairy-cell leukemia had his biological materials, portions of his spleen, and blood samples used in medical research without his knowledge or consent. The research conducted with his biological materials resulted in a cell line that was patented by the defendants who entered into agreements for the commercial development of the cell line and the resulting products. The patient-plaintiff brought suit alleging conversion and breach of physician's disclosure obligations, but the court ruled against the patient. It stated that the defendants had a right to use the plaintiff's cells in medical research, without permission, since there was no ownership interest in cells after they left his body.

The *Catalona* court followed these two cases entirely. It declared that WU had maintained and financed the bio-repository, bore the risks of the research, and asserted its ownership interests through its intellectual property policy. Catalona appealed this decision by the Federal Circuit and took the case to the 8th Circuit Court of Appeals. On June 20, 2007, the 8th Circuit affirmed the District Court of Missouri decision that WU owned the disputed biological materials in the tissue bank, and that Dr. Catalona and

the contributing individuals (RPs) had no ownership or proprietary interest in those biological materials (Supra 1002).

It is important to note that the 8th Circuit affirmed this decision solely on the narrow state law ground (under Missouri law) that the RPs donated their biological materials to WU as inter vivos gifts. The 8th Circuit made no mention of the earlier *Moore* and *Greenberg* cases, of the Common Rule under Title 45 of the CFR, or any other federal regulation relating to tissue donations or research that the District Court used to reach its decision. Since the opinion was based strictly upon state law grounds, it could be deemed of minimal precedential value outside the 8th Circuit and possibly even outside Missouri. Alternatively, it could also stand for the proposition that tissue donation is a state law question that could create 50 different state laws on the subject and potentially set up a state-federal law pre-emption issue that might have to be resolved by the Supreme Court if the circuits split on this issue.

Campbell Plastics Engineering & Mfg., Inc. v. Brownlee and the Bayh-Dole Act

The law continues to develop in the area of balancing Federal rights with those of the inventors of technology under government contracts or grants. The case of *Campbell Plastics Engineering & MFG., Inc. v Brownlee* (2004) turned on the application of the Bayh-Dole Act.

The Bayh-Dole Act allows for the transfer of exclusive control over many government-funded inventions to universities and businesses operating with federal contracts for the purpose of further development and commercialization. The contracting universities and businesses are then permitted to exclusively license the inventions to other parties. The federal government, however, retains *march-in* rights to license the invention (i.e., the right to take over exploitation of the invention where it determines it is not being made available to the public) to a third party, without the consent of the patent holder or original licensee.

Most research institutions are aware that Bayh-Dole allows them to retain title to patent rights in federally funded research. However, they may not know that patent rights can also be lost if the subject invention is not disclosed to the federal funding agency in a timely fashion and pursuant to Bayh-Dole. The case of *Campbell Plastics Engineering & Mfg., Inc. v. Brownlee* deals with this patent issue and involves a federal defense contractor who forfeited his patent rights based on a failure to disclose in a timely manner.

During the time period between September 1992 and September 1994, the contractor filed three reports with the army on form DD 882. In these forms he did not mention his invention, the sonic welding of mask components. From September 1994 through August 1997, the contractor contacted its patent attorney about drafting a patent application on the subject invention; while in the process, he no longer filed reports with the army.

In June 1997, the army published a report (the *June 1997 report*) on research conducted by the army from October 1991 through July 1995, including research on sonic welding of mask components. This report formed the basis for the army's subsequent joint ownership claim, even though the contractor submitted at least 16 progress reports and drawings to the army on his invention. These reports, however, were not submitted on form DD 882.

Over time an exchange of letters took place between the contractor and the

army regarding joint ownership of the invention, and eventually the Administrative Contracting Officer (ACO) for the army concluded that the contractor had forfeited title to the particular patent because of its failure to comply with the patent rights clause by not disclosing the subject invention to the army in a timely fashion.

The contractor appealed the ACO's decision to the Armed Services Board of Contract Appeals. The Board denied the contractor's appeal, ruling: (a) the contractor failed to satisfy its contractual obligation to inform the Army that it considered the sonic welding of mask components to be an invention; (b) any information that the Army learned from its January 1998 review of the subject patent application for its secrecy determination, as well as from its own June 1997 report, was not provided by the contractor, and, thus, forfeiture of title to the patent was appropriate under the circumstances; and (c) while the Army had some discretion in determining whether to take title, it did not abuse that discretion.

In affirming the Board's decision, the Federal Circuit was unsympathetic to the contractor's plea that it had "continually disclosed all features" (Campbell Plastics, 1249) of the subject invention to the army throughout the agreement period. Instead, the Federal Circuit said the agreement's requirement "of a single, easily identified form on which to disclose [subject] inventions is sound and needs to be strictly enforced" (Campbell Plastics, 1249).

As it had argued to the Board, the contractor also argued to the Federal Circuit that the ACO abused his discretion by demanding title because the federal government had allegedly suffered no harm. The Federal Circuit rejected this argument, holding that "harm to the government is not a requirement in order for the ACO to insist on forfeiture and remain within the bounds of sound discretion" (Campbell Plastics, 1250).

In *Campbell Plastics,* the Federal Circuit sent several very clear warnings about complying with contractual obligations based upon the Bayh-Dole Act. For example, loss of patent rights is an appropriate consequence when the contractor fails to disclose the subject invention to the funding agency and the funding agency can dictate, within reason at least, the form of compliance

KSR v. Teleflex

After a long absence from significant activity, the Supreme Court has also returned to delivering important rulings concerning intellectual property (IP). In *KSR Int'l Co. v. Teleflex Inc*. (127 S. Ct. 30; 165 L. Ed. 2d 1009; 2006 U.S. LEXIS 5385; 75 U.S.L.W. 3094 (2006)), the Supreme Court used the *obviousness test* to overturn a decision made by the U.S. Court of Appeals for the Federal Circuit. The Supreme Court ruled that the Federal Circuit had applied the obviousness test too narrowly, and reversed the ruling holding that it was inconsistent with 35 U.S.C.S. §103.

KSR designed a gas pedal with an electronic sensor designed to automatically adjust to the height of the driver. Teleflex sued KSR for patent infringement. KSR argued that it was obvious to look into new methods to make the pedal electronic and use a sensor, and asserted that, because this technology was obvious, the Teleflex patent in question should be invalid.

The U.S. Supreme Court unanimously held that the patent claim was invalid as obvious since mounting an available sensor on a fixed pivot point of the competitor's pedal was a design step well within the grasp of a person of ordinary skill in the relevant art, and the benefit of doing so was obvious.

This decision by the court comes at a time when many commentators are asserting that the U.S. patent system is in need of major changes. Currently, new legislation is being reviewed in Congress that could drastically change the process through which patents are obtained – among other things adopting *a first inventor to file* system rather than the current *first to invent* system, and changing the ease with which patents are granted.

New Legal Models for Research Activity

Beyond the seemingly perennial issues of importance to research, such as control and ownership of information, several new topics are creating a buzz in the legal community and in the management offices of research institutions. One of the topics receiving the most commentary is the increasing prevalence of collaborative research, especially internationally.

Research Collaborations

Researchers and the funding agencies that support them are making headlines with the collaborative work they are engaged in. The Bill & Melinda Gates Foundation and the National Cancer Institute (NCI), for example, are two leading groups that fund collaborative projects designed to enhance the health and well being of people all over the globe. The former, with its Global Access Strategy, has focused its research funding on projects that "create and improve health interventions and strategies to make these interventions accessible to the people who need them most" through the development of "vaccines, drugs, and diagnostics, including basic research, product development, clinical trials, and operations research" (Priority Health Strategies, n.d.).

Currently the foundation is conducting research related to the creation of new methods for treating health problems for which there is no known cure, such as malaria, tuberculosis, and HIV. Complementary research is being undertaken on plans and processes that would make current health methods more affordable and accessible for those who are in need, especially in developing countries.

The NCI is another organization dedicated to helping research move from discovery to delivery by "expanding and facilitating researcher access to resources and new technologies" (Enhancing Investigator, 76, 2004). This institution believes that "the increasing complexity of research projects demands that researchers work in an interdisciplinary team environment, rather than in isolated laboratories with occasional collaborators" (Enhancing Investigator, 73, 2005).

Being able to collaborate with others on issues of global importance, especially in the medical arena, enhances resource sharing, innovation, and the promotion of translational research and intervention development. The NCI supports a wide array of research that will further develop "scientific discovery at the molecular and cellular level" (National Cancer Institute, n.d.).

Agricultural Research Collaborations

Collaborations in agricultural research are essential to protect the environment while ensuring a supply of food to all the populations in the world. Universities, in conjunction with government and grass roots organizations, are developing agricultural practices that improve the quality of food products while enhancing the yield and addressing the environmental impact. Groups such as the Agricultural Research Organization (ARO), International Center for Agricultural Research in the Dry Areas (ICARDA), and the Agricultural Experiment Station (AES) at the University of California, Davis are a few of the

organizations leading the way in agricultural research.

The ARO and ICARDA ensure that representatives from a variety of ethnic groups are able to work together to better develop agriculture methods. For example, the ARO is working in collaboration with groups such as Commonwealth Scientific & Industrial Research Organization (CSIRO), Indian Council of Agriculture Research (ICAR), and The Russian Academy of Agricultural Sciences on numerous research projects based upon shared goals. ICARDA "seeks to improve and integrate the management of soil, water, nutrients, plants and animals in ways that optimize sustainable agricultural production" (Annex 2, n.d.). ICARDA is collaborating with The Arab Center for the Studies of Arid Zones and Dry Lands (ACSAD), Arab Organization for Agricultural Development (AOAD), and the Centro Internacional de Agricultura Tropical (CIAT).

The Agricultural Research Services Office of International Research Programs (OIRP) is another group using research collaboration in the agricultural field. Its projects are designed to "enhance the effectiveness and impact of U.S. agriculture" (ARS, 2006) by:

1. Extending the capacity of national programs to address problems confronting U.S. agriculture;

2. Promoting the participation of those engaged in the scientific community to expedite the exchange of innovations, data and germplasm; and

3. Facilitating international cooperation and collaboration on mutually beneficial, high priority, agricultural research.

In the U.S., governmental organizations such as the National Science Foundation (NSF) are concentrating on collaborative work. International activities are considered an integral part of the NSF's mission to sustain and strengthen the nation's science, mathematics, and engineering capabilities, and to promote the use of those capabilities in service to society. NSF makes grants available to promote the development of international collaborations. Grants from the Office of International Science and Engineering (OISE) also support meritorious, collaborative research and educational activities that offer potentially great benefit because of the vital and integral nature of the foreign collaboration.

Individual universities and research institutions are also promoting collaborative research. For example, the Agricultural Department of the University of California, Davis, Agricultural Experiment Station (AES) supports multiple collaborations involving both the U.S. and other governments, universities and commercial organizations. These programs and others undertaken by research entities across the world are contributing to new bi- or multi-lateral agreements, and even more complex interpretations of the law as it relates to ownership and control of the new and emerging technology.

Cooperative Research and Development Agreement (CRADA)

The Cooperative Research and Development Agreement (CRADA) is a legal agreement between a private company and one or more non-federal parties. The CRADA was "created as a result of the Stevenson-Wydler Technology Innovation Act of 1980, as amended by the Federal Technology Transfer Act of 1986" (Cooperative Research, n.d.). The CRADA allows for "the Federal government and non-Federal partners to optimize their resources, share technical expertise in a protected environment, share intellectual property emerging from the effort, and speed the

commercialization of federally developed technology" (Cooperative Research). It also makes possible the protection of background inventions, trade secrets, and confidential information, and provides for the establishment of intellectual property ownership and licensing options in advance of an invention. The CRADA assists with leveraging federal expertise to develop products with commercialization potential and has the power to enforce agreements it is involved in creating.

A CRADA agreement is used when a "government laboratory and the industry partner collaborate on the development and design of a clinical trial to assess the safety and effectiveness of a study agent (e.g., a drug, medical device, or dietary supplement) for a specific indication" (Cooperative Research, n.d.). Known as a Clinical Trial CRADA agreement or CT-CRADA, this is used when the collaborator designs the protocol, funds the project and is a holder of an investigational new drug (IND).

CRADAs are being used at Department of Veterans Affairs (VA) research facilities located at VA medical centers throughout the country. CRADAs establish the terms of sponsored collaborative research, generally with non-federal industry partners, and are specifically designed to protect the parties' prior inventions while allowing the government and private sector research partner(s) to negotiate management of any new discovery or intellectual property that may result from the collaboration.

The VA highly values its Partnerships for Effective Research for Veterans Health. Whether the collaboration is initiated by VA, a VA principal investigator (PI) or the private sector, a CRADA is a very effective and unique tool. VA's CT-CRADA is the federal government equivalent to a clinical trial agreement (CTA), and allows all parties to realize their objectives while serving veterans and the American public by fostering translation of discoveries into medical practice. It allows access to VA research resources including personnel, services and property.

Informed Consent

With all of the important developments in the law related to research and research administration over the last year, the Office for Human Research Protections (OHRP) has released updated information pertaining to the rules and regulations governing the use of informed consent in research studies.

OHRP recently published an updated set of Frequently Asked Questions and Answers (FAQs) on the subject of informed consent. These guidelines include both regulatory requirements and recommendations. 45 CFR Part 46 states the following general requirements for informed consent:

> Except as provided elsewhere in this policy, no investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the

sponsor, the institution or its agents from liability for negligence (OHRP, 2005).

In its FAQ, OHRP notes that informed consent is legally effective if it is obtained from the subject or the subject's legally authorized representative and documented in a manner that is consistent with both the HHS protection of human subjects regulations and applicable laws of the jurisdiction in which the research is conducted.

In response to a related question, OHRP holds that it is possible, under the circumstances noted below, to obtain legally effective informed consent to research in an urgent or emergency care setting. In an urgent or emergency care setting, the answer would depend upon: (a) the expected medical condition of the prospective subject population, (b) the nature of the research, (c) the time allowed for the potential subjects or their legally authorized representatives to consider participation, and (d) the circumstances for obtaining informed consent appropriately minimize the possibility of coercion or undue influence (Human Research Questions, n.d.).

It is also possible to waive consent in an emergency care setting. Under 45 CFR 46.101(i) (and consistent with FDA 21 CFR 50.24), OHRP has authorized a waiver of the requirement for obtaining and documenting informed consent for research that may be carried out in human subjects who are in need of emergency therapy and for whom, because of the subjects' medical condition and the unavailability of legally authorized representatives of the subjects, no legally effective informed consent can be obtained.

As the world continues to advance technologically, the question of whether or not informed consent can be documented by an electronic signature has also been raised. According to the updated FAQs, an electronic signature may, under certain circumstances, be accepted as documentation of informed consent. The investigator and the institutional review board (IRB) need to be aware of laws governing electronic signatures in the jurisdiction where the research is being conducted. OHRP will allow electronic signatures of the consent if such signatures are legally valid within the jurisdiction of the research and if the signature is properly obtained. In the university setting it is important to know the rules governing the use of electronic signatures for consent, as many studies these days are available to students to complete online.

In addition to the use of electronic signatures, university researchers need to be aware of the numerous rules governing the participation of student subjects in research studies. When enrolling students into research studies the amount of coercion or undue influence must be kept to a minimum. OHRP recommends that universities have policies that clarify for students and faculty that any participation by students in research must be voluntary. Reasonable levels of extra credit or rewards may be offered for participating in research. If extra credit or rewards are offered, or if participation is a course requirement, students must be given the option of pursuing non-research alternatives involving comparable time and effort so that undue influence is minimized. An important rule is that students (indeed, all research subjects) must not be penalized for refusing to participate in research (45 CFR 46.116(a)(8) OHRP, n.d.).

Guidelines governing the enrollment of employees in research are similar to those governing the enrollment of students. According to OHRP, he investigators and IRBs must be cautious about the potential for coercion or undue influence and the need to protect confidentiality. Freedom

of choice may be undermined when employees are faced with deciding whether or not to participate, particularly when that decision could affect performance evaluations or job advancement. Employees may experience coercion if they feel that refusal to participate could lead to a loss of benefits, or undue influence if a decision to participate could result in a job promotion. Both employers and researchers must ensure that the decision to participate or not has no effect on the employees' jobs.

The information listed here is just a brief introduction into OHRP's FAQs regarding informed consent. For additional information, these and more FAQs may be accessed at: http://www.hhs.gov/ohrp/faq.html.

Conclusion

President Harry Truman (1948) once said that:

> Continuous research by our best scientists is the key to American leadership and true national security. This work may be made impossible by the creation of an atmosphere in which no man feels safe against the public airing of unfounded rumors, gossip and vilification.

His comments resonate even today as noted by the AAU (Ehringhaus, Owens, Smith, & Turman, 2003), which suggests that:

> Increasing restrictions on the communication of and participation in research, including agency efforts to create new categories of sensitive but unclassified research and to insert restrictions through regulations and through clauses in contracts, threaten the core university value of openness in scientific research.

This openness may be at risk of being compromised even though most Americans would agree that national security is of the utmost importance. Nevertheless, "the defense authorities have very good reason to know that the scientific community has proved its respect for the national security through three hot wars and a long cold one. That respect must be reciprocated" (Carey, 1982). Given the positive impact that research has had on the health of Americans, their economy, and their safety and security, legislators must carefully weigh the consequences of policies that reduce the ability of researchers to conduct their work.

Ever-changing legislation and regulations governing how research is handled are certainly a challenge for today's researchers and research administrators. By understanding the changes in laws related to data collection and dissemination, through the sharing of information such as what has been included in this article, The Society of Research Administrators International will continue to help research administrators keep abreast of these developments.

References

15 CFR chapter VII, subchapter C. Export Administration Regulations (EAR).

15 CFR chapter VII Part 764, Supplement 3; See also 15 CFR chapter VII Section 744.1(c).

22 CFR Parts 120-130. International Traffic in Arms Regulations (ITAR).

22 CFR § 121.1. United States Munitions List (USML).

22 CFR § 121.1 Category VIII.

45 CFR 46.116(a)(8) "OHRP - Code of Federal Regulations"

2002 CFR Title 31, Volume 2 Chapter V. Office of Foreign Assets Control (OFAC).

§734.2(b)(2)(ii) of the Export Administration Regulations. "Deemed Export Rule".

PL 96-517, Patent and Trademark Act Amendments of 1980. Bayh-Dole Act.

Annex 2: ICARDA Regional Networks. Retrieved August 1, 2007 from http://www.icarda.org/CWANA+Partnership/CWANA+SSP.html

ARS Office of International Research Programs (OIRP). (2006). Retrieved August 1, 2007 from http://www.ars.usda.gov/research/docs.htm?docid=1428

Campbell Plastics Engineering 7 Mfg., Inc. v. Brownlee, 389 F.3d 1243 (Fed. Cir. 2004)

Carey, William D. (1982) *Handcuffing Science*. Science Magazine. Volume 217, Issue 4566.

Clinical Technology Transfer Group, P.L.L.C. (CTTG). "Cooperative Research and Development Agreement (CRADA)". Retrieved August 1, 2007 from http://cttg-law.com/cradas.shtml.

Cooperative Research and Development Agreement (CRADA). Retrieved August 1, 2007 from.http://www.usgs.gov/tech-transfer/what-crada.html.

Deemed Export FAQ's. Retrieved August 1, 2007 from http://www.bis.doc.gov/deemedexports/deemedexportsfaqs.html#1.

Defense Trade Function Overview. (no date) Retrieved August 1, 2007 from http://www.pmddtc.state.gov/

DFARS Case 2004-D010. (2006), AAU Comments. Retrieved August 1, 2007 from http://www.aau.edu/research/Ltr_AAU_DFARS_10-13-06.pdf.

Ehringhaus, S., Owens, M., Smith, T., & Turman, R. (2003). AAU Memorandum: Homeland Security Workshop-Summary and Action Steps. Association of American Universities. Retrieved August 1, 2007 from http://www.ncsu.edu/sparcs/export/aau_workshop.doc .

Enhancing Investigator Initiated Research. (2004). Retrieved August 1, 2007 from http://plan2004.cancer.gov/capacity/investigator.htm.

Enhancing Investigator-Initiated Research. (2005). Retrieved August 1, 2007 from http://plan2005.cancer.gov/investigator.html.

"Final Inspection Report No. IPE-16176-March 2004". (2004). Office of Inspector General. Retrieved August 1, 2007 from http://www.oig.doc.gov/oig/reports/2004/BIS-IPE-16176-03-2004.pdf.

Greenberg, et. al. v. Miami Children's Hospital Research Institute, Inc., et. al., 264 F. Supp. 2d 1064 (S.D. Fla. 2003)

Human Research Questions & Answers: Informed Consent, Question 1, 9. (2007) Retrieved August 1, 2007 from http://answers.ohrp.hhs.gov/cgibin/answers_ohrp.cfg/php/enduser/std_alp.php

KSR Int'l Co. v. Teleflex Inc. 127 S. Ct. 30; 165 L. Ed. 2d 1009; 2006 U.S. LEXIS 5385; 75 U.S.L.W. 3094

Madey v. Duke Univ., 307 F.3d 1351, 2002 U.S. App. LEXIS 20823 (Fed. Cir., 2002), overturning *Madey v. Duke Univ.,* 1999 U.S. Dist. LEXIS 21379 (MDNC 1999)

Moore v. The Regents of the University of California, et. al., 51 Cal.3d. 120, 793 P.2d. 479, 271 Cal.Rptr. 146 (CA. 1990).

National Cancer Institute Mission. Retrieved August 1, 2007 from http://www.nih.gov/about/almanac/archive/2002/organization/NCI.htm

National Security Decision Directives (NSDD). (1985). Retrieved August 1, 2007 from http://www.fas.org/irp/offdocs/nsdd/.

OHRP - Code of Federal Regulations. Retrieved August 1, 2007 from http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm

Prah, Pamela. Oklahoma cracks down on illegal immigrants. (2007). Retrieved August 1, 2007 from http://archive.stateline.org/flash-data/blurbs.html#OK

Prah, Pamela. State legislatures reflect election changeover. (2007).

Retrieved August 1, 2007 from http://www.stateline.org/live/printable/story?contentId=214708

Priority Health Strategies. Retrieved August 1, 2007 from http://www.gatesfoundation.org/GlobalHealth/Grantseekers/GH_Strategy/Strategy_Grantmaking.htm

Revision and Clarification of Deemed Export Related Regulatory Requirements Bureau of Industry and Security, Commerce, 15 CFR Parts 734 and 772 (RIN 0694-AD29). (2005). Retrieved August 1, 2007 from http://www.aau.edu/research/AAU_Comments_on_Export_Controls-06-27-05.pdf

The Inspector General Act of 1978, 5 (1978). U.S.C.A. Appendix 3. Office of Inspector General (OIG). Retrieved August 1, 2007 from http://www.aau.edu/research/AAU_Comments_on_Export_Controls-06-27-05.pdf.

The Immigration and Compliance Act 06 SB529/AP. (2006). Retrieved August 1, 2007 from http://www.legis.state.ga.us/legis/2005_06/fulltext/sb529.htm.

Truman, President Harry S. (1948) Address to the Centennial Anniversary AAAS Annual Meeting. Retrieved July 18, 2007 from http://www.aaas.org/spp/yearbook/chap2.htm.

Wash. Univ. v. Catalona, 437 F. Supp. 2d 985, 2006 U.S. Dist. LEXIS 22969 (ED Mo., 2006), overturning Wash. Univ. v. Catalona, 2007 U.S. App. LEXIS 14442 (8th Cir. Mo., June 20, 2007)

Voice of Experience
International Research Infrastructure and The Impact of Export Control Regulations

2007 Coordinator and Senior Writer
Elliott C. Kulakowski, Ph.D.

2007 Authors/Contributors
Lynne Chronister, MPA
Victoria Molfese, Ph.D.
Michael Slocum
Cliff Studman, Ph.D.
Paul Waugaman

Authors' Note
The authors wish to thank Ms. Amanda Boddie for her assistance in preparation of this article.

Abstract
Research today has become very complex, often involving international collaborations among multidisciplinary teams. Many institutions, especially those in less economically developed countries, have a great deal of expertise to contribute to these collaborations, but often lack the instrumentation, training, and research management infrastructure needed to support their endeavors. While non-profit organizations provide assistance with instrumentation and training to support the research infrastructure, efforts from the United States are hampered by Export Control Regulations. An appropriate balance is needed to develop research collaborations with universities in other countries while protecting United States security interests.

Introduction
Administrators International (SRA) celebrates its 40th anniversary. Originally founded as a North American organization, with four sections in the United States and one in Canada, SRA has grown into a truly international society. To reflect its growing global membership, SRA added the term "International" to its name in 2000. Members today come from nearly every part of the world (Table1). As SRA has increased its international membership and diversity of research management interests, it has remained dedicated to its mission of training and career development for research managers and administrators through formal educational offerings, exchange of best practices and continual networking among members.

The face of research, too, has changed over the years. Seldom is research confined to a single team working at one laboratory. As research has become more complex, sub-specialties have developed in scientific disciplines, and special expertise in using complex research procedures and instrumentation is critically important. Not every institution can afford the increasing cost of highly sophisticated instrumentation, such as nuclear magnetic resonance spectroscopy (which can reach hundreds of thousands of dollars, even before maintenance and personnel costs), and funding sources are not able to pay such costs. This has led to the growth of multidisciplinary, collaborative research that is no longer confined to a single laboratory or nation, but involves multiple institutions internationally.

Table 1

Countries with Representation in Society of Research Administrators International

Algeria	Georgia	Moldova	Spain
Armenia	Germany	Netherlands	Sweden
Australia	Ghana	New Zealand	Tanzania
Azerbaijan	Hong Kong	Nigeria	Thailand
Botswana	India	Pakistan	Ukraine
Brazil	Ireland	Republic of South Africa	Uganda
Cambodia	Israel	Russia	United Arab Emirates
Canada	Jamaica	Scotland	United Kingdom
Denmark	Japan	Senegal	United States
Egypt	Kazakhstan	South Korea	Uzbekistan
England	Kenya	Southwest Africa	Virgin Islands
Finland			

As the complexity and globalization of research have grown, regulations governing research also have become more complex. Institutions in the United States and elsewhere have learned to deal with the regulatory and policy differences attendant with the globalization of research. To meet the needs of universities and other organizations engaged in research, SRA has provided training and professional development opportunities to improve the research management infrastructure of institutions throughout the world.

It has been said that the path to economic and human development in a global knowledge economy is through increased education. Organizations such as the U.S. Civilian Research and Development Foundation (CRDF), the Carnegie Corporation, and the John D. and Catherine T. MacArthur Foundation support efforts to increase the capacity for higher education and research in Africa, states of the former Soviet Union, and elsewhere. These groups support the research efforts, complex equipment, and the development of research management infrastructure at universities and other organizations needed for international collaborations. Other U.S.-based foundations, such as the Bill & Melinda Gates Foundation, the Rockefeller Foundation, and the Ford Foundation, have invested heavily in developing local solutions to local and global problems through research.

Despite the continued efforts of these groups and others to support research organizations and researchers, United States Export Control Regulations can be a barrier to collaborations between scientists in the U.S. and around the world. Understanding these restrictions is critical if we are to engage in global research.

This article describes United States Export Control Regulations and the needs of international researchers for access to training, the latest technologies, and the infrastructure support of their home institutions. Examples of the needs of universities in Africa, Russia, and states of the former Soviet Union are presented.

An appropriate balance must exist among the U.S. need for national security, support for educational advances in other countries, and advances in research that can only be achieved through international collaborations.

An Overview of Export Control Laws and Regulations

Current U.S. export laws control dissemination of a wide range of technologies in a way that may have an adverse impact on research and the ability of international researchers to perform competitively. U.S. laws and regulations control the conditions under which certain information, technologies, and commodities can be transmitted overseas to anyone, including U.S. citizens working overseas, or to a foreign national, even if he or she is working in the U.S.

Export Administration Regulations

The responsibility of the Bureau of Industry and Security (BIS) in the Department of Commerce is to apply and enforce the Export Administration Regulations (EAR), which implement the Export Administration Act of 1979 (Export Administration Regulations Database). The EAR is responsible for regulating the export and re-export of many commercial items, including those often referred to as "dual-use." Dual-use items have both military and commercial applications. Some examples of these items are software, chemicals, and technologies such as aircraft power transmission systems. A list of these items can be found on the BIS webpage (Export Administration Regulations Database).

A small percentage of U.S. exports and re-exports that the EAR regulates require a license from BIS. There are 10 specific categories that require a license: nuclear materials; chemicals, microorganisms, toxins; materials processing; electronics; computers; telecommunications; lasers and sensors; avionics; marine; propulsion systems. The requirements for a license depend on, among other things, what item is being exported, where it is going, who is going to receive it, and how will it be used.

International Traffic of Arms Regulations

The mission of the International Traffic of Arms Regulations, or ITAR, is the control of arms sales to foreign parties to protect U.S. national security and to further U.S. foreign policies (22CFR120 – 130). The regulations of defense items are overseen by the U.S. Department of State. ITAR is responsible for regulating export and import of defense items that the United States Munitions List (USML) covers, or items that are inherently military in nature (designed to kill/defend against death in a military situation). ITAR also serves as a judge for license applications for exports, dealing with matters related to defense trade compliance and enforcement, and making reports on defense trade available to Congress and the public.

ITAR has 21 categories that require a license, including weapons, chemical and biological agents, vehicles, missiles, equipment, and all satellites. Among the problems ITAR can create for research organizations includes the expansion of its jurisdiction to research satellites, related technology and data. Universities that had been developing their own research satellite capabilities now must deal with an export regime applied to spy satellites and military rocketry.

A second issue for research organizations is the increasing application of ITAR to the life sciences. For instance, after 9/11 applications of export control regulations to research quantities of bacterial specimens were considerably stricter due to heightened national security.

Office of Foreign Assets Control
The Office of Foreign Assets Control, or OFAC, is part of the Department of Treasury. OFAC is responsible for administering and enforcing economic and trade sanctions. These sanctions are governed by U.S. foreign policy and national security goals in defense against terrorists, drug traffickers, and the proliferation of weapons of mass destruction. OFAC has the authority to impose controls on transactions and to freeze foreign assets; these controls can be either comprehensive or selective.

OFAC regulations often provide general licenses authorizing the performance of certain categories of transactions (Foreign Assets Control Regulations). OFAC also issues specific licenses on a case-by-case basis under certain limited conditions. OFAC oversees limited transactions referred to as "prohibited transactions," which are trade, financial and other dealings in which U.S. persons may not engage unless authorized by OFAC or expressly exempted by statute. However, each program is based on different foreign policy and national security goals, so the prohibitions may differ between various programs. Generally, a license may be required any time a research collaboration involves a person with citizenship in, or institution located in, one of several countries (e.g., various countries in the Balkans, Belarus, Burma, Cote d'Ivoire, Cuba, Democratic Republic of the Congo, Iran, Liberia, North Korea, Sudan, Syria, and Zimbabwe), and there are contractual or financial dealings.

The National Policy on the Transfer of Scientific, Technical, and Engineering Information - NSDD 189
The National Policy on the Transfer of Scientific, Technical, and Engineering Information, or the National Security Decision Directive (NSDD) 189, holds that the products of fundamental research are to continue to be unrestricted. This policy, created under the Reagan administration in 1981, defines fundamental research as: "the basic and applied research in science and engineering, the results of which ordinarily are published and shared broadly within the scientific community, as distinguished from proprietary research and from industrial development, design, production, and product utilization, the results of which ordinarily are restricted for proprietary or national security reasons."

The NSDD 189 provides that:

> Where the national security requires control, the mechanism for control of information generated during federally-funded fundamental research in science, technology and engineering at colleges, universities and laboratories is classification. Each federal government agency is responsible for: a) determining whether classification is appropriate prior to the award of a research grant, contract, or cooperative agreement and, if so, controlling the research results through standard classification procedures; b) periodically reviewing all research grants, contracts, or cooperative agreements for potential classification. No restrictions may be placed upon the conduct or reporting of federally-funded fundamental research that has not received national security classification, except as provided in applicable U.S. Statutes. (National Policy on the Transfer of Scientific, Technical, and Engineering Information)

This clause from the NSDD 189 is important because it maintains that fundamental research that has not been classified as important to national security must remain free and unrestricted. If the national security interest is important enough to trump the need for open transfer of information in support of research, the Directive requires

that the information be protected under the National Security Classification system.

Federal Research Exclusion

In response to academic concerns that export control regimes would stifle basic research, the Federal government created the Fundamental Research Exclusion to allow free transmission of solely fundamental research information that is already available in the public domain to full-time employees of an institution or university for educational instruction. This exception to the application of the various export control regimes applies only to information that is published and in the public domain, and only in the U.S. at accredited institutions of higher learning. According to Eric Iverson at a Public Policy Colloquium in 2002, "In the absence of this policy, universities would need an export license for each foreign student matriculated, each foreign researcher invited, and each collaboration with a foreign institution." (Iverson, E., 2002).

The Fundamental Research Exclusion can be lost in a federally funded project where a university accepts specific national security controls. Under the EAR, as opposed to the ITAR, the exclusion may not be lost even if a university accepts greater restrictions on its rights to disclose. However, the scope of pre-emption of the regulatory exclusion is not clear, and universities should never accept contract or grant language that purports to override the Fundamental Research Exclusion.

The Fundamental Research Exclusion also applies to full-time employees under ITAR. This allows disclosures of unclassified technical data in the U.S. by U.S. universities to foreign nationals who are bona fide, full-time regular university employees whose permanent residence throughout the period of employment is in U.S. However, this exemption may not be applied when the employee is a national of an embargoed country. Some of ITAR's embargoed countries include Afghanistan, Belarus, Cuba, Iran, Libya, North Korea, Syria, and Vietnam. In addition, ITAR allows the employee exemption only when the university informs the employee in writing that data may not be transferred to other foreign nationals without government approval. There are additional limitations. Some researchers, such as graduate or doctoral students, may not have full-time employee status, and some types of visas may require holders to maintain foreign residence.

National Security in Conflict with Global Interests

The problem for researchers and research administrators that arises from regulations such as the EAR and ITAR is the expansive definition of "export." Understanding when export controls apply, when a license is required, and when there are no exemptions available is problematic because of the complexities of agencies, policies, and range of covered activities and materials. To engage in non-fundamental research collaborations, institutions must obtain a license before export-controlled items or information can be shared abroad or on a U.S. campus with foreign nationals participating in the research. When restricted countries are involved, there may be no licenses available at all. The destinations most often subject to restriction include both major powers such as China, India, Israel, Pakistan, Russia, and countries that are often the site of international collaborations: various countries in the Balkans, Belarus, Burma, Cote d'Ivoire, Cuba, Democratic Republic of the Congo, Iran, Liberia, North Korea, Sudan, Syria, and Zimbabwe. Other restrictions apply to conferences only where unpublished research is presented, such as who can attend or co-sponsor the meeting. Institutions will face even more restrictions

when the activities involve teaching foreign collaborators how to use items in research ("defense service") or when transfers of research equipment abroad is proposed.

In his 1948 address to the Centennial Anniversary of the American Association for the Advancement of Science Annual Meeting, President Truman said,

> Continuous research by our best scientists is the key to American leadership and true national security. This work may be made impossible by the creation of an atmosphere in which no man feels safe against the public airing of unfounded rumors, gossip and vilification. (Truman, 1948)

To bring these issues all into perspective, the following quote from the Association of American Universities, made during a homeland security workshop, conveys the impact of the above mentioned policies and regulations.

> Increasing restrictions on the communication of and participation in research, including agency efforts to create new categories of 'sensitive' but unclassified research and to insert restrictions through regulations and through clauses in contracts, threaten the core university value of openness in scientific research. (Ehringhaus, Owens, Smith, and Turman, 2003)

What Is Being Done

There is a considerable need for education and the development of international research collaborations by economically less-developed countries. Some successes have been achieved, but there is a tremendous opportunity to do considerably more. There are many challenges facing research faculty and administrators from less developed countries as they try to build and sustain world-class research programs. This includes the need for additional training, availability of the latest technologies, the opportunity to collaborate with investigators in the United States and elsewhere, and support for their research programs. The following examples describe some international efforts that have yielded successes, the greater challenges ahead, and the need for additional collaborations and support for research, its infrastructure and its management.

African Experience

The Association of Commonwealth Universities has reported in a survey of African universities that only one reported submitting between 250 and 500 proposals annually, low by American standards for a research institution (Kirkland, J. 2005). However, universities in Africa are very interested in building their research programs and research management infrastructure (Stackhouse, J. Sultan, J., and Kirkland, J. 2001). In particular, the Carnegie Corporation provided support for SRA International to bring six chief executive officers from universities in Ghana, Nigeria, Tanzania, and Uganda to the United States in the spring of 2003 to learn about research management and meet with U.S. federal research funding agencies. The goal was to enable all participants to learn more about the American research management system and to begin to build collaborations between American and African universities. These meetings, held at the Northeast Section of SRA, at universities in the United States, and at federal agencies in Washington, D.C., were followed by week-long training workshops in research management at the six Carnegie partner universities between June, 2004 and March, 2006. Workshops were organized and presented by SRA members. An example of the building of the research management infrastructure in Nigeria is discussed below.

In another program, the Carnegie Corporation is supporting a project that aligns SRA with the Association of Commonwealth Universities and the Southern African Research and Innovation Management Association to engage a number of universities in a year-long needs assessment and planning exercise to develop a comprehensive plan for staff development and education in research management for universities across the African Continent.

Nigerian Experience

Nigeria is the most populous nation in Africa, and has a system of over 80 national universities, many of which were established at the time the country became independent in 1961. The Nigerian national universities are awakening from nearly 20 years of neglect by their federal government. Once thriving research centers such as Ahmadu Bello University, Bayero University and the University of Ibadan, have an aging faculty, outdated equipment for which parts are no longer available, and decaying laboratories. Some faculty and students conduct manual experiments, much as they did in the 1960s. Some equipment that is available cannot be installed because of the cost of laboratory renovation and the training of staff to operate the instruments. Another hardship is that dependable electric power is always subject to fluctuations, which can strain components of state-of-the-art instruments. Supplying back-up generator power to an entire university is not an effective solution due to the unaffordable cost of diesel. These power interruptions and fluctuations result in loss of computer services, with the result that many experiments must be repeated.

Despite these hardships, there are some re-emerging pockets of world-class research. Research efforts are supported by limited university funds and monies provided by the MacArthur Foundation and the Carnegie Corporation. These funds partially support faculty development, the purchase of new equipment, and the development of research infrastructure, such as information and communications technology networks and improved reference libraries. For instance, at Ahmadu Bello University, there is a thriving nuclear energy research program supported by the government that may one day enable the country to provide reliable power throughout the region.

The virology research program at the University of Ibadan is focusing on HIV and malaria research in very sophisticated biosafety level II and III laboratories with modern equipment provided by the Bill & Melinda Gates Foundation. This lab and others at the university medical center have continuous electrical power supported by a grant from the World Health Organization.

The Nigerian universities are establishing a number of collaborations with institutions in the United States and Europe. In particular, the University of Ibadan has about 40 international collaborations and receives National Institutes of Health (NIH) funding through subcontracts from universities in the United States. However, any international collaborative program only operates successfully if there is adequate funding for both the U.S. institution and its Nigerian collaborator. Often funds are available for the U.S. partner, but unless there is some mechanism for channeling money to enable the African partner to participate, the collaboration has little value. The African universities must learn research management to meet federal flow-through requirements. Fortunately, some sponsors are realizing the reality of the situation, and finding ways to resolve the issue.

At present, the Nigerian universities have only small pockets of research. To increase the breadth of their research programs,

they need access to the latest laboratory instrumentation and extensive training in state-of-the-art techniques. This can be accomplished through collaborations in the United States and elsewhere. The Nigerian universities also are conscious of the need to develop and implement a research management infrastructure.

SRA International, with support from both the MacArthur Foundation and Carnegie Corporation, is working with seven Nigerian institutions to build their research management capacity. The MacArthur Foundation, in May 2007, sponsored representatives from SRA International to conduct site visits of MacArthur-sponsored Nigerian universities. The goal of the site visits was to review their research programs and research management infrastructure, discuss research management with them, and identify two universities that would gain the most by sending a delegation to the United States to visit American universities to build research collaborations and learn how American Universities conduct research management. In addition, the delegations are to attend the 2007 SRA International Annual meeting and visit U.S. federal government funding agencies.

The Former Soviet Union

At the time of the fall of the former Soviet Union, universities and research institutes in Russia, Georgia, Kazakhstan, Moldova, Ukraine and other newly independent countries were left without public support. Research programs that once were directed by officials in Moscow were left to flounder. In the early 1990s, a major threat to world stability was the possibility of unintentional transfer of Soviet weapons technology. The solution has been to encourage the conversion of the former Soviet research enterprise from a defense and weapons basis to a more peaceful basis. This is being accomplished by encouraging research and development in computer science, advanced materials, and other fields of science where former Soviet researchers are internationally competitive, and by building research competence in agricultural, biomedical, and natural resource sciences, which can improve local public health, food production and resource management. It is hoped that such activities are able to raise standards of living and promote economic development.

Through the efforts of the United States government and several private foundations, a non-profit organization, the U.S. Civilian Research and Development Foundation (CRDF) was established. CRDF is funded by the National Science Foundation, the State Department and other federal agencies. The mission of CRDF is to foster and to maintain the research efforts of leading scientists in the countries of the former Soviet Union by providing them with limited research funding, modern laboratory equipment and training to support their research programs. CRDF has partnered with SRA International to provide training for scientists and research managers, both in their home countries and in the United States. SRA International members from the University of California Davis, the University of Kentucky, San Diego State University, Utah State University, the Medical University of South Carolina, the University of Liverpool, the Research Administration and Management Strategy Group, Inc., the Technology Commercialization Group, LLC and elsewhere have helped train research and technology managers from 16 Russian universities and research center directors from university institutes and independent research organizations from countries of the former Soviet Union.

In these ways, SRA International serves the global research management profession

by providing basic skills, disseminating best practices, and encouraging and enabling productive collaborative research that will increase the pace of scientific discovery by mobilizing brain power across the world, and promote the economic and social development of all parts of the world through the advance of knowledge-driven economies by skilled people.

Blending Research, Economic Development and U.S. National Security

Over the past 20 years there has been increasing recognition globally that the way university research is managed, as distinct from the research itself, can play a critical role in the success of universities and their impact on society (Kirkland, 2005). This is especially evident in the experiences we have witnessed in Africa and states of the former Soviet Union.

In a meeting sponsored by CRDF in November, 2006 in Almaty, Kazakhstan, leaders from over 20 research centers from states of the former Soviet Union were able to show how they have utilized the research equipment provided by CRDF to build their research program; two even reported that they were able to develop and license technologies based on their research. For example, a research institute in Kazakhstan has been able to develop solar panels with a much higher efficiency than what is normally achieved. This may result in a new company to produce and commercialize the panels. Another research center discussed how it has utilized research equipment for not only research purposes, but also to market its expertise and make its equipment available to industry. This center has generated over $1 million in income and is reinvesting the money to support research projects, expand laboratories, purchase new equipment and hire additional staff. The positive economic impact in these two cases could not have been possible without the equipment provided by CRDF and the training that their research scientists received in the United States and elsewhere.

Through generous donors, Nigeria has some of the latest instrumentation and technology for conducting HIV research. The training of scientists in the United States and in Europe is invaluable to these scientists as they have built collaborations. This has allowed the University of Ibadan to receive support from the NIH through subcontracts from academic institutions in the United States. The training of these investigators, their collaborations with scientists in the United States and the state-of-the-art equipment they have available for their research is having a major impact on their universities and on the next generation of graduates, and potentially will impact economic development within the country.

The examples above only highlight the types of research that are being conducted at foreign universities in some countries. However, what we discussed here is only a small portion of what is happening around the world. Research programs sponsored by the NIH are global — either through research subcontracts from U.S academic institutions or through the Fogarty International Center, which provides training opportunities in the United States for foreign nationals. The NIH also is seeking to build the research management infrastructure in countries such as India so that its research programs can be effectively and efficiently managed. The National Science Foundation (NSF) also supports international research efforts, and has sent delegations to China and elsewhere to discuss issues of research management. The research supported by these two federal sponsors adds new knowledge to the areas of research that are within the missions of the federal agencies. In addition, it is hoped that support of these research activities may lead

to new products and processes, such as the development of new pharmaceutical agents for the treatment of malaria. The ability of countries to collaborate with scientists from other areas of the world is necessary for the development of their people and for the impact education and research can have on their economy.

Looming over these very exciting and productive collaborations and initiatives, however, are questions central to the Export Control Regulations. Could the equipment and laboratories be used for nefarious purposes? Could the training received by the international researchers be applied to purposes other than those allowed? The answer to both of these questions is – Yes, but! — and this is a large "**but.**" Generally, it has been observed that knowledge and expertise that are used to gain new knowledge and applied to the health and economic welfare of people in the nations involved must be considered.

There is an undeniable need to maintain national security, both in the United States and other countries. However, it is important to balance technological innovations and knowledge expansion with societal needs and applications of that knowledge and technology. Universities and research institutions must have workable export policies and the knowledge to enforce them. Faculty must be aware of their purposes and follow the policies, and research administrators must lead efforts to provide appropriate training and ensure compliance.

Universities have always held to the "fundamental research exemption," but post 9-11 the National Science Foundation reported that the number of foreign graduate students admitted for study to the United States had declined. This has since reversed. As reported in the Chronicle of Higher Education, "to the relief of college researchers, the U.S. Commerce Department has abandoned a plan that would have restricted foreign students' and scholars' access to sensitive technology based on their countries of birth rather than their countries of citizenship or permanent residency. This is and will make a very large impact on future scientists from these countries, but from other countries as well." (Field, K. 2006).

Conclusion

We live in a world where international research collaborations are expanding nearly every day. Fundamental research provides new knowledge about the world in which we live. This knowledge may eventually find application and be translated into new products and processes. Research may lead to new ways to improve crop production to feed people, to a new understanding about disease processes and new therapies, and new products and processes that can improve a country's economy.

In this article we discussed a few examples of the positive impact from collaborations between institutions in the United States and elsewhere. The success of these programs not only aids the United States, but also has an impact on the collaborating country. Basic research collaborations and training of future scientists from less developed countries must be encouraged and supported.

While there is a need to maintain national security in the United States, an appropriate balance must be met. The dialogue must continue among agencies within the federal government that sponsor research and those that are responsible for export control regulations. Any discussion also must include leaders in academic administration, faculty, and representation from organizations such as the American

Association for the Advancement of Science, Council on Government Relations and the National Association of State and Land Grant Colleges. The appropriate balance will not only raise the economies of less developed countries, but will also aid the United States.

References

22CFR120 - 130 Retrieved August 26, 2007, from http://www.access.gpo.gov/nara/cfr/waisidx_05/22cfrv1_05.html.

Ehringhaus, S., Owens, M., Smith, T., & Turman, R. (2003). AAU Memorandum: Homeland Security Workshop-Summary and Action Steps. Retrieved August 26, 2007, from www.ncsu.edu/sparcs/export/aau_workshop.doc

Export Administration Regulations Database. Retrieved August 26, 2007, from http://www.access.gpo.gov/bis/ear/ear_data.html.

Field, K. (2006). Commerce drops plan to limit researchers. *The Chronicle of Higher Education*. Retrieved August 26, 2007, from. http://chronicle.com/weekly/v52/i21/21a02501.htm.

Foreign Assets Control Regulations. Retrieved August 26, 2007, from http://www.access.gpo.gov/nara/cfr/waisidx_02/31cfr500_02.html.

Iverson, E. (2002). ITAR Briefing Paper. Retrieved August 26, 2007, from http://www.asee.org/conferences/erc/presentations/upload/ITAR-Briefing-Paper.doc.

Kirkland, J. (2005). The demand for research management support in African universities. Retrieved August 26, 2007, from www.acu.ac.uk/resman/pdf/App3BackgroundPaper.pdf.

National Policy on the Transfer of Scientific, Technical, and Engineering Information. Retrieved August 26, 2007, from http://www.fas.org/irp/offdocs/nsdd/nsdd-189.htm.

Truman, H. S. (1948). Address to the Centennial Anniversary AAAS Annual Meeting. Retrieved August 26, 2007, from http://www.aaas.org/spp/yearbook/chap2.htm.

Stackhouse, J., Sultan, J., & Kirkland, J. (2001). Research management in African universities. Retrieved August 26, 2007, from http://www.acu.ac.uk/resman/pdf/ResearchManagementinAfricanUniverities.pdf

Research Administrators Certification Council

The Research Administrators Certification Council was formed in 1993. It is an independent non-profit organization. The Council is composed of active certified research administrators. The designation of Certified Research Administrator (CRA) means that an individual has met the Council's eligibility requirements and has demonstrated a level of knowledge necessary for a person to be a professional research or sponsored programs administrator.

CRA Review sessions are currently scheduled at various U.S. locations.

Check www.cra-cert.org to find a session near you. If you are interested in holding a CRA Review session at your institution, contact us at racc@ptcny.com.

The benefits of certification are many:

- **Professional recognition**
- **Personal satisfaction**
- **An indicator of expertise**
- **Increased opportunities for employment**
- **Advancement opportunities**
- **Increased credibility with clients**
- **Serve as a role model to others**

www.cra-cert.org Phone: 212-356-0693 racc@ptcny.com

Patrons

Platinum

Michael Owen

Gold

Dr. Edward F. Gabriele

Kathleen Hogue Gonzalez, CRA

Dr. Phillip E. Myers

PROFESSIONAL RESULTS

Prepared by Graphics Production Services
at The Henry M. Jackson Foundation
for the Advancement of Military Medicine, Inc.

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

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