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In This Issue

The subjects of the articles in this issue range from the practical, in the case studies of faculty development programs and strategic planning and a basic primer for those unfamiliar with subcontracting, to the theoretical, in the commentary and research papers concerning ethical considerations of research. The types of institutions represented by the authors include universities, research institutes, government agencies, and a medical college, and the articles will provide interest for a range of readers, from the relatively inexperienced to senior research administrators, for pre-award and to deans and educational coordinators or training personnel.

Certain issues appear to be of wide and enduring interest to research administrators. One of these is how to help new investigators improve their grant writing and increase their rate of success in applying for grants. The three case studies on the topic of faculty development programs in this issue show unique features. The Porter article, “Off the Launching Pad: Stimulating Proposal Development by Junior Faculty,” is a case study of a program in which the grants office of Virginia Tech designed special workshops to stimulate more submissions to selected programs by new faculty to help them initiate their research careers. In the Gordin article, “A Development Program for Junior Faculty Submitting National Institutes of Health Grant Applications,” the department of medicine at Baylor College of Medicine developed a pre-submission review program of junior faculty NIH applications to improve their success rate and increase the amount of NIH funding to the department. The third paper on this topic, “An Innovative Program for Cultivating Grant Writing Skills in New Faculty Members,” is a roundtable discussion by eight members of the faculty of the University of Northern Colorado, Marilyn Banta, Robin Brewer, Arlene Hansen, Heng-Yu Ku, Kimberly Pacheco, Robert Powers, Julie Robinson, and Gardiner Tucker, Fellows of the faculty fellowship program designed by the University’s sponsored projects office.

A very practical paper for new research administrators, or in fact any research administrators with little or no experience of subcontracting, is “Subcontracting Primer: The ABCs of Agreements Between Collaborators,” by Marie Smith of the Institute of Ecosystem Studies. This commentary describes how lead institutions should administer subcontracts and ensure compliance with Circular A-133 or other circulators for novices in subcontract administration.

Research administrators continue to wrestle with ethical issues of research, and two papers address these issues in specific areas of research. Caines and Gabriele’s “Two Roads Converge: The Challenge of Human Subject Protections In the Forensic DNA Research Context” conveys the authors’ concerns about complex issues surrounding privacy and confidentiality in DNA profiling from the federal and state points of view. The second, “Protecting Sex Partners in Partner Notification and Management Studies” by S. Semaan and S.O. Aral of the Centers for Disease Control and Prevention and A. Klovdahl of Australian National University, explains the ethical principles, especially beneficence, involving sex partners notification and management studies.

The final paper by I. Goodman, “Planning in an Academic Matrix Research Center,” is a case study explaining the effectiveness of strategic planning in a complex environment involving research, academic, and patient care at the Rebecca and John Moores UCSD Cancer Center of the University of California, San Diego.
Contributors

Robert Porter, PhD, is a Program Development Manager with the Research Division at Virginia Tech. A former college teacher, Dr. Porter spent nearly twenty years with private consulting firms, specializing in strategic planning, organizational development and grant writing. At Virginia Tech, he assists faculty with proposal development and funding searches and conducts workshops on various topics related to sponsored research. He holds graduate degrees in Speech Communications from the University of Michigan.

Barbara Gordin, CRA, is a Senior Administrative Associate in the Department of Medicine at Baylor College of Medicine in Houston, TX. She heads the pre-award research office in the department, providing funding and policy information, assisting in preparation and review of grant applications, and coordinating training seminars to faculty and staff at five affiliated institutions. Additionally, she served as the first Executive Director of the International Atherosclerosis Society from 1990-1997. Ms. Gordin began her career as a Grants and Contracts Management Specialist at the National Institute of Child Health and Human Development, National Institutes of Health. She has served as a site visitor for the National Institutes of Health as well as a consultant for state and local agencies. Ms. Gordin was in the first group nationally to be awarded designation as a Certified Research Administrator in 1993. She received her BA from American University, Washington, DC, in history and secondary education.

Heng-Yu Ku, PhD, is an Assistant Professor in the Department of Educational Technology at the University of Northern Colorado. Originally from Taiwan, Dr. Ku received his PhD in Learning and Instructional Technology from Arizona State University. Currently, Dr. Ku is the project director of the Preparing Tomorrow’s Teachers to Use Technology Grant at the University of Northern Colorado and teaches Instructional Design, Computers in Education, and Doctoral Seminar in Educational Technology courses. Dr. Ku has presented multiple papers at national and international conferences and has a well-established publication of research record.

Marie F. Smith, CRA, is Manager of Grants Administration at the Institute of Ecosystem Studies in Millbrook, New York. Since assuming this role in 1998, she has been responsible for pre- and post-award administration, contract negotiation, subaward management, grant accounting, and A-133 audits and now assists with compliance issues. In 2001 she became a Certified Research Administrator. Recently, Ms. Smith has been charged with leading a series of discussion groups on topics in Responsible Conduct in Research for the Institute of Ecosystem Studies, using the case study approach. Ms. Smith holds an Associates and a Bachelors Degree in Accounting and Management from the State University of New York. Ms. Smith is a board member and board officer of several local nonprofit agencies and is a member of SRA, NACUBO and NCURA.
Vaughan Caines, MSc, was born in Bermuda and is currently a resident of the United States. He attended Hofstra University on Long Island New York, where he received his BA in Biology in 1989. After graduation he continued to study Molecular Biology on the graduate level at his Alma Mater, and has worked professionally in the teaching, research and environmental fields. In 2000 Mr. Caines graduated from the University of Strathclyde in Glasgow, Scotland with a MSc in Forensic Science and is currently working for the State of New Hampshire Department of Safety as a Forensic Toxicologist. Mr. Caines is also finishing up his doctoral studies in Law and Science at the University of Newcastle upon Tyne in the United Kingdom.

Edward Gabriele, DMin, serves as the Professional Integrity and Ethics Special Consultant to the Navy Surgeon General and the charter Director, Office of Professional Integrity and Ethics, Bureau of Medicine and Surgery, Washington, DC. In this role he is responsible for assisting Naval Medicine activities throughout the world with the coordination, integration, development, and promotion of policies, services, and educational programs relative to academic and applied healthcare ethics, research integrity, organizational ethics, and core values formation. Among these activities he is the Director of the Naval Medicine Human Research Protections Program. Dr. Gabriele holds an appointment as Adjunct Assistant Professor in the Department of Preventive Medicine and Biometrics at the Uniformed Services University in Bethesda, MD providing consultations in research ethics. Dr. Gabriele holds a bachelor of science degree in communications secondary education and a bachelor of arts degree in religious studies both from Villanova University, a master’s degree in theology from The Catholic Theological Union in Chicago, and a doctorate in theology from The Catholic University of America in Washington, DC. Dr. Gabriele is a member of the SRA Distinguished Faculty and the Chair of the SRA Symposium for contributed papers and poster-abstract presentations. In 2001, he received the SRA Award for Excellence. Both in 2001 and in 2002, he received consecutive year Society Awards for Best Concurrent Session for his educational lectures at the Society’s annual meetings. In addition, Dr. Gabriele is a member of the Leadership Council of the Responsible Conduct of Research Education Consortium. For the Consortium and for SRA International, Dr. Gabriele chairs the SRA Responsible Conduct of Research Special Interest Group.

Salaam Semaan, DrPH, is deputy associate director for science in the Division of Sexually Transmitted Diseases Prevention (DSTDP), Centers for Disease Control and Prevention (CDC), Atlanta, Georgia. Before her appointment in the DSTDP, Dr. Semaan worked as a behavioral scientist in the Division of HIV/AIDS Prevention at CDC. Prior to her move to Atlanta, Dr. Semaan worked in Philadelphia, Pennsylvania, as a senior research associate with Philadelphia Health Management Corporation and as a research associate with the University of Pennsylvania. Dr. Semaan worked also as a primary health care officer with Save the Children Federation in Beirut, Lebanon and as a survey researcher and analyst with the Ministry of Health, Manama, Bahrain. Dr. Semaan has co-authored more than 40 articles on HIV prevention. She also co-edited the supplement “Do Behavioral HIV Interventions Work? A Review and Meta-Analysis” published by the Journal of Acquired Immune Deficiency Syndromes, 2002, 30 (Supplement 1): S1-S136. Her primary research interests include the science and ethics of HIV and STD prevention and her research studies were with different populations at risk for infection with HIV and STDs, including women and drug users. Dr. Semaan received her doctorate in public health from the Johns Hopkins University, Baltimore, Maryland.
Ira S. Goodman, MPA, MS, is Associate Director for Administration of the Rebecca and John Moores UCSD Cancer Center at the University of California, San Diego, having assumed the post in 2001 after relocating from New York City.

Mr. Goodman began his academic administration career at NYU Medical Center as the administrative coordinator of the Departments of Psychiatry and Neurology. He was recruited to New York University School of Medicine central administration as a manager in the Office of Grants and Contracts Administration, eventually becoming the director. Mr. Goodman has written extensively on research administration and made numerous presentations at conferences and seminars. He was awarded in 1997 the Society of Research Administration’s Rod Rose Award as lead author for best publication of the year (Enhancing Communication in a Multi Campus Research Center). He has also served on national, local and professional group advisory boards including the NIH, NYC Health & Hospitals Corporation, AAMC, and SRA. He is now a member of the Executive Committee of the Cancer Center Administrators Forum. Mr. Goodman has a Bachelor of Science degree with majors in Biology and Chemistry from Long Island University and Master of Public Administration and Master of Science (Clinical Management) degrees from the NYU Wagner School of Public Service.
Announcements

Journal Publication on Web

At the SRA Annual Meeting in October, 2003, the SRA International Board of Directors approved a change in the way this journal will be published. Beginning with 2003, two numbers will be published each year. Beginning with this current number, all numbers of the journal will be published on the Web; at the end of the year the two numbers will be compiled into one volume and printed and mailed to all members and subscribers.

In the past, each number was posted to the SRA Web site after printing and mailing. The second number of 2003, volume 34, no. 2, was the last number to be printed and mailed as a separate number. This current issue, volume 35, number 1, is the first one to be published first on the SRA Web site and will not be printed and mailed as a separate number. At the end of the year, both of this year’s numbers will be compiled into one volume and printed and mailed as the annual volume for 2004.
Case Study

Off the Launching Pad: Stimulating Proposal Development by Junior Faculty

Robert Porter
Virginia Tech

Abstract
With pressure mounting to increase extramural funding, new faculty become increasingly important to the overall effort, as this group has the greatest potential to add to the university’s future crop of award winners. Ominously, evidence shows that those who fail to establish effective habits of research and writing early in their careers probably never will. The challenge new faculty present to research administration can be simply put: What is the best means to get them started on their research careers? This paper describes an approach led by the grants office that uses specially designed workshops to demystify sponsored research, build collegiality among new faculty and their more experienced colleagues, and stimulate greater participation in selected grant programs.

The Challenge
For research administrators, encouraging more proposal submissions is a constant challenge, and it is largely a game of numbers: The more proposals a given faculty member writes, the more likely s/he will find success. The higher the percentage of faculty who are actively developing proposals, the greater the growth in the university’s research budget. Published data tracking the level of faculty activity in grant writing are scarce, but at many universities there is plenty of room for growth. A 1992 study of eight state colleges in New Jersey showed only 20% of the faculty were actively engaged in sponsored research that year (Monahan, 1993). At Virginia Tech, less than 50% of the combined research and teaching faculty submitted proposals in 2003, not a comforting ratio for a research university with ambitions to rise in the national rankings.

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In pursuing the goal of getting more faculty to generate more proposals, grants specialists are bound to trigger some degree of resistance, as inactive faculty definitely have their reasons for not writing grants (Miner et al., 2003). New faculty are a special challenge. Fresh out of graduate school and landing their first teaching positions, newcomers can be overwhelmed by their dual responsibilities to teach and publish. It has long been recognized that the first years of teaching are highly stressful for new faculty, and that the pressing demands of preparing new classes, advising and supervising students, all while adjusting to an entirely new environment at work and at home, are among the reasons that many put research and scholarship on a backburner (Gibson, 1992). Focused on developing new course materials and building their bibliographies, and feeling as though they’ve been plunged into a sink-or-swim environment, many are chagrined to learn their employer has yet a third daunting expectation: sponsored research. Even those in the science and engineering disciplines who made their way through graduate school as research assistants can often display only a dim awareness of how the money to pay their tuition and stipends was obtained. Finally, as Freedman et al. noted more than two decades ago, research and scholarly activities are harshly competitive, resulting in a faculty culture that is a “fairly grim affair, and is becoming increasingly so” (1979). The danger here is that those who fail to establish effective habits of research and writing early in their careers probably never will (Creswell, 1985).

Building on Recognized Needs

Strategies to activate junior faculty in grant writing can build on findings from several major studies. First, these are early career professionals whose dominant concerns are advancement and promotion, and this can be an exciting period in their work lives as they strive to carve out an area of specialization, move up professionally, and make a name (Baldwin, 1990). Second, this group recognizes its own need for training. A survey of academics asked respondents what they believed would best develop young faculty members. Seventy-nine per cent of junior faculty participating in the survey identified training as a priority need (Jarvis, 1991). Third, a considerable body of research supports the contention that collegiality is the most important single factor in faculty development. Sadly, participation in a supportive community of scholars, what the historian Page Smith has called “the pursuit of truth among friends,” appears to be in short supply on many campuses, a deficit that junior faculty have identified as a significant barrier to their development (Jarvis, 1991; Smith, 1990; Turner & Boice, 1987). Taken together, this research suggests that to be successful a coordinated program to enhance proposal development should immerse new faculty in a series of workshops that feature interactions with senior faculty role models. Why workshops, as opposed to other modes of instruction? Briefly, it has to do with a workshop’s superior capabilities to provide learning opportunities in several domains at once—knowledge, skills, and attitudes. Properly designed, an interactive workshop combines the immediacy of problem-centered instruction with opportunities for reflection, analysis and discussion (UNESCO, 1985).

Junior Faculty Workshops: Principles of Design

In the spring of 2001, the grants office at Virginia Tech adopted the philosophy that a single new faculty workshop scheduled only occasionally or once a year is insufficient. On the theory that information intended to change mindsets and work habits has to be conveyed repeatedly, we decided to launch a sequential series of workshops scheduled throughout the year. Given the general intent to create such a series, we settled on four design principles:

1. Celebrate success

To combat the strong cultural impediments to grant writing, it is critical to instill more positive attitudes and create higher expectations for success. Success stories from more experienced faculty, especially those who are just a step or two ahead of the novices in their career development, can have a powerful effect.
2. Expand horizons
Narrow and biased views toward sponsored research can be expanded by emphasizing the multiple advantages of external funding. Professor Dan Inman (2000), a consistently successful grant writer at Virginia Tech, presents a persuasive case:

There are several good reasons to seek funding for your work. The first is the practical one that if you are successful you greatly enhance your chances of tenure and promotion. The second reason is that you can use your funding to greatly increase your academic freedom. Having funds can allow you to recruit the best students, work with the best computers and software, travel to the most important conferences, afford page charges in the best journals, buy the best equipment, secure timely secretarial services, maximize the time you can devote to research (buy out courses) and in general have the freedom to do many more things than can be done on a typical university faculty member’s budget. You can also secure funds to pay your summer salary and hence increase your annual salary up to 33%. (Ch. 3, p. 1)

3. Clear up the mysteries
Grant writing can seem an arcane talent to many who are new to the enterprise. To demystify the process, workshops should focus on a small number of basic writing tips, most of which stress simplicity, clarity and a preference for plain English over dense academic prose. Examples of successful writing should be freely distributed, including entire copies of winning grants.

4. Focus on reviewer(s)
As the keys to the kingdom of funded research lie in the inner workings and hidden mechanisms of review panels, the human dynamics of the grant review process should be featured in every program: How do review panels operate? What are reviewers looking for? What do they like? What annoys them? Informal presentations by experienced panelists are the best means to convey useful answers to these questions.

5. Parse the directions
Since failure to do so is one of the documented reasons for early proposal rejection, workshops should stress key steps (and missteps) in proposal preparation for specific agencies.

A Sequential Series
Following an introductory session aimed at instilling positive attitudes and identifying support services (Your Research Career: Getting Started), Virginia Tech implemented skill development workshops (Writing Successful Grants, Finding Funding), then targeted specific programs and sponsors (NSF CAREER Award, Building the NIH Grant). Though the programs were designed with junior faculty in mind, registration was open, and we were pleased to note significant attendance by senior faculty. The table to the right lists the programs, their objectives, and summaries of their formats.

Enlisting Experienced Faculty
Wherever possible, we have enlisted experienced, grant-savvy faculty as featured workshop presenters and panelists. The intention is to present them as positive role models and potential mentors, willing to take time to share their insights and demystify the entire process. Thankfully, most have been quite willing to participate, and their presentations, as well as the lively Q&A sessions that follow, are invariably the high points of any given workshop. While we don’t say so explicitly, this is a singularly powerful way to build collegiality and strengthen the research culture of the university. For example, in designing the “Getting Started” workshop, we went to our list of “heavy hitters,” those faculty who consistently land major awards year after year. (At Virginia Tech, 20% of the faculty generate 80% of sponsored research dollars.) The format consisted of a general introduction to grant writing, then a description of services provided by the sponsored research office, followed by a senior faculty presentation entitled “Secrets of My Big Fat Research Career,” scheduled last because we knew none of us could follow that act!

In another example, we enlisted three previous winners of the NSF CAREER Award
to discuss proposal writing strategies that led to their success, all of whom were just a year or two ahead of workshop attendees in their academic careers. The NIH Mock Panel Review was especially effective in stimulating energetic dialogue between junior and senior faculty, as several buzz groups remained after the workshop. Building on this model, we plan to introduce mock review panels for NSF and USDA during the 2003/4 academic year.

Feedback and Outcomes

Workshop evaluations have been uniformly positive, and average ratings on a five point scale have been running from 4.3 to 4.6, with 4 meaning “good” and 5 “outstanding.” Written comments show that presentations by senior faculty and previous grant winners are by far the most popular, and complete paper copies of successful grants, including all required forms, are widely appreciated. While data to track the actual impact of these workshops are hard to come by, we are gratified by two trends: (a) In two years, funding searches on the Community of Science database more than doubled, jumping from 26,600 in 2001 to nearly 55,000 in 2003, (b) for NSF’s CAREER Award program, proposals submitted increased from 9 in 2000 to 23 in 2002, and awards went from 4 to 7 over that same period, a majority of the authors of which attended the workshops. Since these are five year awards averaging more than $125,000 per year, they lend a substantial boost to young academic careers.

A Matter of Timing

When introducing the sponsored research office and the workshop schedule, forget about orientation. New faculty orientation at the start of the fall semester is the worst possible time to talk about sponsored research. Any presentation by the grants office is likely to be drowned in the deluge of information being dumped on the hapless newbies by earnest speakers pitching everything from retirement plans to football tickets. Much better time slots are the weeks

| Table 1. A Series of Proposal Development Workshops for Junior Faculty |
|-----------------------------------|-----------------|------------------|
| Workshop Title | Purpose | Format |
| I. Setting the Stage | | |
| Your Research Career: Getting Started | Instill positive attitudes toward sponsored research; enhance awareness of support services | Presentations by grants specialist, sponsored research officer and senior faculty with outstanding records in sponsor awards |
| II. Skill Development | | |
| Writing Successful Grants | Develop basic writing skills; avoid common proposal pitfalls | Lecture and discussion; evaluate examples from successful and unsuccessful proposals |
| Finding Funding | Use searchable databases (Community of Science, Foundation Center) to identify potential sponsors | Computer lab with online terminals; instructor demonstration followed by participant practice sessions |
| III. Program Specific | | |
| Virginia Tech ASPIRES Program | Clarify purpose of internal grant program, review application procedures | Presentations by program officers; panel discussion by recent award winners |
| NSF CAREER Award | Clarify program purpose, proposal review criteria and critical success factors | Review program announcement, distribute copies of successful proposals; presentations by recent award winners |
| IV. Agency Specific | | |
| Building the NIH Grant | Clarify NIH mission, application guidelines and review procedures | Review NIH application kit, examine excerpts from successful proposals; presentations by successful NIH grantees |
| NIH Mock Panel Review | Demonstrate working process of an NIH “panel” | Senior faculty with NIH review experience evaluate proposal abstracts submitted by participants |
between mid-semester and finals, or the week just prior to the start of the next term, when new faculty have enough breathing room to focus properly on the third leg of their academic careers. Program-specific workshops should be scheduled four to six months ahead of the submission deadline.

Conclusions

A series of sequential workshops targeted to younger faculty can be powerful tools in enhancing the university’s research culture. High levels of attendance, combined with very positive written and oral feedback, are encouraging indicators that junior faculty appreciate these developmental experiences. Additionally, the active participation of senior faculty is evidence of their sincere interest in mentoring younger colleagues, even those from other disciplines. Finally, these events offer repeated opportunities for research administration to present itself in a helping role, serving as a catalyst for collegiality as well as a supplier of ongoing support services.
References


A Development Program for Junior Faculty Submitting National Institutes of Health Grant Applications

Barbara Gordin
Baylor College of Medicine

Abstract

Five years ago, the Department of Medicine at Baylor College of Medicine initiated a multi-faceted, pre-submission review process of junior faculty members’ National Institutes of Health (NIH) grant applications. This case study summarizes the program; the problems encountered, both from the junior faculty the program was intended to help and the senior faculty who were to be facilitators; adjustments along the way; the NIH funding results; reflections on the merits and shortfalls; and possible future directions.

Introduction

The Department of Medicine at Baylor College of Medicine has over 100 active faculty researchers in 20 Sections and Programs. The Department’s Pre-Award Research Office is a separate area of departmental administration providing, among other things, information to new faculty and staff on pre-award services, guidance in identifying funding opportunities, budgetary and administrative review, communication on research issues, and educational sessions. Common sense and good grantsmanship would ensure that all grants submitted by junior faculty were reviewed carefully by the section/program chiefs, mentors, and collaborative faculty. However, this was not being consistently done, partially due to vacancies in the section chief positions. Therefore, in an effort to improve the NIH “hit” rate, in July 1998 Dr. Andrew I. Schafer, Chair, and Dr. Glenn Cunningham, Vice Chair for Research,

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introduced a departmental-wide, mandatory program to the section/program chiefs at their monthly executive faculty meeting; the program was initiated later that year. Dubbed the “junior faculty review process,” the program involved an internal and external review of new and competing NIH research (R01 only) and career (K) proposals submitted by instructors and assistant professors, regardless of their age or prior/current holding of an NIH grant. This process was intended to supplement, not supplant, the section/program review. The junior faculty were still expected to have mentors and section/program chiefs review their proposals.

**Guidelines**

The guidelines were as follows: two months before the NIH standard submission deadlines, a good draft of the application was to be submitted to our office. Because of time considerations, junior faculty could apply to RFAs and RFPs without going through the internal review. Competing applications would also go through the full departmental review process. Two reviews would be performed. One would be a scientific review, with the applicant choosing a senior investigator outside his or her section/program, since the senior investigators within the section/program should already be reading the proposals. The reviewer could be anyone, giving applicants the opportunity to contact someone well known in their field. Pre-Award Research Office personnel would contact the reviewer and explain our purpose and process. The other review would be a readability review, involving a more senior member of the department whom we had chosen, again not in the applicant’s section/program. Both reviewers should return the marked-up proposal within two weeks from receipt; local reviewers were encouraged to meet with the junior faculty. Since many of the junior faculty did not speak English as a first language, if any of the reviewers felt that the proposal needed extensive English editing, they were to notify us and we would provide an editor.

The reviewers would be paid $150 for the review (subsequently increased to $200). In the event the reviewer’s suggestions resulted in an application’s being extensively revised, the reviewer could request to see the proposal after the changes had been made. We would then pay an additional $100 for the second review.

Applicants were encouraged to meet with a biostatistician on our staff if they did not have the requisite expertise. The staff biostatisticians were salaried; therefore any investigator could use their services without charge in the application stage. Two years into the process, after the biostatistical group disbanded, our office began paying a biostatistician to review the proposals.

**Implementation**

We sent a letter and a page explaining the procedures to every instructor and assistant professor in the department and the administrative assistants of each section/program. A former section chief interested in mentoring agreed to be the readability reviewer for several proposals each cycle. We made a list of all associate professors and professors in the department who were involved in research, including those with secondary appointments in our department, since they would be potential readability reviewers, and sent a letter to all of the potential readability reviewers explaining the program and enlisting their support.

When proposals involved in the process arrived at our office, we immediately sent them (either by hand-delivery or courier service) to all reviewers with a letter explaining why we had implemented the process; an instruction sheet tailored to whether they were doing the readability or scientific review; and for those outside of the institution, a contractor form to sign for payment.

Information regarding the applications was stored in a Microsoft Access database. Items included 1) faculty information—the targeted submission date, faculty name, identification number, and section/program; 2) reviewers’ information—name, date we first contacted them, date the proposal was sent to them, date it was received back, how much they were paid for the review, and how payment was made (salary supplement, check, or unrestricted account); and 3) NIH information—proposal title, and eventually, proposal number, priority score and percentile.
Initial Roadblocks

The issue of whether the department could refuse to allow submission of a proposal that did not comply with the review process was discussed with the Office of Research (OOR) at the College. Since all proposals submitted by the College must have a Department Chair (or designee) approval, the OOR agreed that they would not sign a proposal which the Department had not approved. The Department has not had to withhold a proposal from submission. On the few occasions where a proposal was submitted without the formal review process, there was some legitimate reason.

Many junior faculty were not happy with the new policy and made statements such as “It’s mildly irritating when one realizes that certain senior faculty will continue to wait to the last minute,” and “I have received 12 years of NIH funding so please explain why someone needs to hold my hand while I apply for my next one?” But the Chairman had decided that all junior faculty would participate.

Ongoing Issues

Problems often arose in finding readability reviewers. Although the section/program chiefs had initially endorsed the program, not all were enthusiastic about being a reviewer. Excuses ranged from “Use me as a last hope,” to “I send my own proposals to someone else to read,” to submitting their own proposal that cycle, or being a reviewer for an NIH Study Section with many proposals to review. Our resident senior reviewer tremendously eased this burden; however, in cycles where many junior faculty were submitting proposals, we were often reduced to begging for reviewers. After a shipping error sent a proposal to the wrong continent, we changed the rules so that the scientific reviewer chosen by the junior faculty member had to be located in North America.

Although the instructions are available on the department website and we send the link to all junior faculty three times a year when we remind the faculty of upcoming deadlines, some still misinterpret. We can attribute some of these misinterpretations to the English-as-a-second-language investigators; the rest are assumed to result from problems adhering to instructions. Several sections believed that they could handle the review as well within the section. These were well-organized groups, with strong section/program leadership and biostatisticians. Therefore, within a few years the reviews for these groups were returned to them. The department has tracked their proposal success rate, although so far the number of applications is insufficient to provide statistical significance.

A year-and-a-half after the program began, we recognized that a biostatistical review could not remain optional, since the applicants were not taking advantage of the service available to them. Many, especially bench scientists, believed that their proposal did not need this input. We then required that the proposals also be submitted to our biostatisticians, along with the scientific and readability reviewers. If the biostatisticians agreed that the proposal contained nothing for them to review, the applicant was so notified. In many cases, however, the biostatisticians uncovered issues that should have been addressed. Our current biostatistician has sent applicants such tactful comments as, “Although disagreeing about the need for biostatistics in this particular proposal, an argument exists for at least a minimum attention to such matters”, and “Your proposal may not succeed or fail because of absence of biostatistical content; however, it should normally be included and would make the proposal easier to read and understand.” (J.I. Thornby, personal communication, January 13, 2003)

Since the program started, just over $45,000 has been paid to the reviewers. We estimate that approximately 30% of a staff member’s time is spent on the junior faculty review process, including sending reminder announcements every cycle, lining up the readability reviewers, distributing the grant applications to all reviewers, answering numerous questions from the junior faculty, and processing payments to the reviewers. The two most vexing aspects of our process recur every review cycle: the litany of reasons by the junior faculty of why the proposal can’t be turned in on the review deadline and the senior faculty’s reluctance to being readability reviewers.
Assessment

Four years after the start of the process, we sent a questionnaire to the junior faculty asking them to rate the reviewers. The names of all of their reviewers were listed, including the scientific ones. Even though the junior faculty members had chosen the scientific reviewers, their assessment was equally important, since someone in the future might choose the same reviewer. If a faculty member had submitted multiple applications, a separate page was used for each application. A numerical scale, using 1=excellent to 4=poor, was used for the following criteria: turnaround time of the reviewer’s critique; quality of critique provided by the reviewer; quality of interaction with reviewer; overall effectiveness of the reviewer; and overall effectiveness of the review process. Additionally, the junior faculty were asked if the reviewer should be used again. Space was provided for comments and suggestions. We entered the scores into a spreadsheet and tabulated a cumulative score for each reviewer. Any reviewer rated poorly by more than one junior faculty member was deleted from the list of available reviewers.

We also sent a survey to the senior readability reviewers explaining that candid assessment would help us refine the process. We used the same rating scale for these criteria: was there enough time to review the proposal; did they think their review helped improve the quality of the proposal; if the proposal was reviewed a second time, were recommendations sufficiently incorporated; if they met with the applicant, was the interaction beneficial; was our payment to them fair; and overall effectiveness. And again, we provided space for comments and suggestions.

By receiving the NIH Summary Statements from the junior faculty, we have an opportunity to address areas that need improvement. No summary statements indicated that the proposal was poorly written (except for one very contradictory summary statement which said, “the application is poorly written” on one page and then “highly polished and well-written application” on the next page), so we think that the readability of the proposals has improved. The summary statements from the K series have been especially valuable. Comments regarding letters of recommendation not showing enough institutional commitment or not stating a plan for growing independence will prove helpful in future submissions as we review those sections more carefully.

Funding Results

During the period studied (through 2002), seven proposals were evaluated by our reviewers as not developed enough to be submitted to NIH. Of the remaining 75 initial applications submitted to NIH, 16 initial applications were funded. Of those, eight were K awards (67% of all the initial K proposals submitted), reflecting a higher success rate during this period than the national average (NIH, n.d.). The R01 rates, however, were not stellar. One can rationalize this to result from external funding factors, but regardless of how readable a proposal is, nothing will compensate for science that is not stellar.

Originally we did not include resubmissions in our review, assuming that applicants would address the concerns of the NIH Study Section and render the review unnecessary. Several of our junior faculty had, however, voluntarily requested that their NIH resubmissions undergo our review process. Three years into our review process, after reviewing our funding data, the most clear-cut results turned out to be in the category of resubmissions. Of the eight resubmitted applications that went through the departmental review process, 50% were funded, higher than the national average (NIH, 2003), with 25% unscored. Of the 11 resubmitted applications that did not go through the departmental review process, only 18% were funded, with 36% unscored. Therefore, we decided that all junior faculty resubmissions would go through an abbreviated review process. Unless the NIH Summary Statement provided evidence to the contrary (such as needing more statistical input), only the original readability reviewer would review the proposal again. Using the Summary Statement as a guideline, the reviewer would determine whether the applicant responded appropriately to the Study Section’s concerns.
Conclusion

When much of the material contained in this article was presented at a recent Executive Faculty meeting, the section/program chiefs strongly favored retaining the program. However, due to recent budget and staff reductions, we are assessing where our resources can make the most impact. Our approach may need to be refined and better targeted. Most particularly, we are looking at focusing on K applicants and the areas of specialized help—including biostatistics and English editing for those whose first language is not English.

An important payoff of the process is the collaboration that many of the junior faculty have established with their reviewers. Additionally, the junior faculty are submitting a better product, albeit not always funded. By requiring them to think more critically as they go through the reviews, we are contributing to ensuring that the junior faculty become better proposal writers. “Hit” rates, the original motivator, cannot be the only measure of the value of a process.

References


Case Study

An Innovative Program for Cultivating Grant Writing Skills in New Faculty Members

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Abstract
The Sponsored Project and Research Center Office at the University of Northern Colorado developed the Sponsored Project Development Award (SPDA) Fellowship Program as one piece of its internal grants program. The design for the Fellowship Program is an amalgamation of ideas garnered from a study of other institutions’ faculty development and internal grants programs. The Fellowship Program provides new faculty members with a research development account and involves them in a two-year series of hands-on development activities related to grantsmanship and proposal writing. In 2003, seven Fellows were selected through a competitive application process. This article is a roundtable discussion about various aspects of the SPDA Fellowship.

Introduction
One of the primary missions of sponsored programs offices in both public and private universities is to encourage faculty to apply for external grants. In these days of budget shortfalls, universities are asking their faculty to take on additional teaching loads, often at the expense of time that could be dedicated to grant writing, just when the financial gains to the university from external grants would be most valuable. This provides an interesting challenge to sponsored program officers: how to encourage writing grant proposals and develop grantsmanship in faculty, especially new faculty, during these tough financial times.
The Sponsored Project and Research Center (SPARC) Office at the University of Northern Colorado has developed an innovative program designed to encourage and support grant writing activities in young faculty. The Sponsored Project Development Award (SPDA) Fellowship Program is a two-year fellowship designed for new faculty. Faculty members submit applications to the SPARC Office, which then reviews the applications and selects a group of SPDA Fellows to begin the fellowship together as a cohort. The Fellowship makes certain demands on the fellows during the two-year program, but it also provides the fellows with a variety of incentives to aid in their grant writing development. The Application Form Cover Page, which describes the requirements and benefits of the program, is included as Appendix A. Note that both the department chair and the dean must sign off on the application, thereby guaranteeing both their financial and logistical support for the fellow while he/she participates in the program.

In Spring 2003, the SPARC Office chose a cohort of seven faculty to participate in the SPDA Program. This paper contains a description of how the SPARC Office developed the SPDA Program and garnered support for the program from the university administration. It also contains direct feedback on aspects of the SPDA Program from the seven current fellows including information on the diversity of backgrounds represented by the fellows, perceptions of the pros and cons of the program, and suggestions for improvement.

**Conception and Support for the SPDA Program**

The SPARC Office at the University of Northern Colorado developed the Sponsored Project Development Award Fellowship Program as one piece of its internal grants program. Begun in the fall of 2001, the goal was to increase the number of faculty members who were writing successful grant proposals. The design for the Fellowship Program was an amalgamation of ideas garnered from a study of other institutions’ faculty development and internal grants programs and from professional presenters at grant-writing workshops. The method was to bring in ten young faculty members with a desire to become involved in grant proposal writing, to provide them with a research development account, and to involve them, as a cohort, in a year-long series of intensive and hands-on development activities related to grantsmanship and proposal writing. The goal was that when these individuals became successful at getting grants, they would then go on to mentor others.

Funding for the program came from the portion of indirect cost recovery retained by SPARC for faculty development. In addition, each of the six deans was asked to contribute $500 from their college toward a research development account for each Fellow. The budget for the program was $40,000, or $4,000 per Fellow, to cover the costs of proposal writing workshops, travel to Washington, visits to mentors, research development accounts of $2,000 per fellow (in addition to the $500 from the deans), and a variety of other development meetings and activities.

To encourage buy-in of the program at the college level, each dean was asked to nominate the Fellows from his or her college. The result was an original cohort composed of eleven faculty members (an increase of one from the originally planned ten) from five colleges and the libraries, and from eleven different disciplines. From the onset, there were difficulties working with a group of that size comprised of individuals who had not volunteered, but had been nominated to participate. One Fellow asked to be removed from the program after the first month because he simply was not interested. Finding common meeting times for ten Fellows was next to impossible, and the group did not bond as a cohort. Some Fellows continued to work at learning grantsmanship and writing proposals, but many of the planned activities did not take place and the goal of the program was not met.

The idea of a grant development cohort did not die, however; and after reviewing and redesigning the program, it was initiated again in the spring of 2003. The Fellows were selected through a competitive application process designed to assure that those selected as Fellows would be individuals who were not only interested, but also qualified and ready to participate in a newly designed two-year program.
The seven Fellows participating in the Spring 2003 SPDA Program are all assistant professors from different disciplines. They are Dr. Marilyn Banta, Department of Biological Sciences, College of Arts and Sciences; Dr. Robin Brewer, Division of Exceptionalities and Bilingual/ESL Education, College of Education; Dr. Heng-Yu Ku, Department of Educational Technology, College of Education; Dr. Kimberly (Kim) Pacheco, Department of Chemistry and Biochemistry, College of Arts and Sciences; Dr. Robert (Rob) Powers, Department of Mathematical Sciences, College of Arts and Sciences; Dr. Julie Robinson, Department of English, College of Arts and Sciences; and Dr. Gardiner Tucker, Division of Educational Leadership and Policy Studies, College of Education. The remainder of this article is a roundtable discussion involving the seven members of the Spring 2003 cohort about various aspects of the SPDA Fellowship Program.

**Impetus for Applying to be an SPDA Fellow**

In this section the fellows describe why they were interested in applying for the SPDA Fellowship. In addition to the incentives the program provides, the applicants generally were interested in learning more about grant proposal writing and improving their grantsmanship skills.

**Rob:** I applied for the SPDA Fellowship as an incentive to increase my scholarly activity. I had a colleague in the mathematical sciences department who was a member of the first cohort. She recommended that I apply because of the incentives: the release time during one semester, the $600 in start-up funds, and the mentorship model of grant writing. From the little information I received from her, however, the first SPDA Fellowship did not seem to be going too well. I think the administrators of the program learned quite a bit from the first cohorts, which they have applied to ours.

**Robin:** Like Rob said, the course release was very attractive and will be helpful for me in continuing my goal to write a grant proposal to the U. S. Office of Special Education Programs. I know the importance of getting grants and how grant funds can assist a faculty member with dissemination, up-to-date equipment, and support for the additional staff to help us in partnership schools. I am not very disciplined when it comes to finding the time to write. I am hoping the accountability to my fellow SPDA Fellows will provide me with the incentive to write more grant proposals. An unexpected outcome so far has been meeting others in the university that I would have otherwise not met. Collaborating on projects, such as this one, would have not been possible for me without the SPDA Fellowship.

**Heng-Yu:** I hesitated to apply for the SPDA fellowship at first because I did not feel that I was qualified. To be honest, the incentive motivated me to apply for it. I am interested in seeing how people pull everything together in a cohesive way to write grant proposals. I also would like to find a mentor or mentors who can give me advice and guide me through the grant writing process.

**Kim:** I applied to the SPDA Fellows program because I wanted more support in the area of writing grant proposals. The department of chemistry feels that it is important for the new people in the department to submit proposals, but there is not a rich history of grant writing in the department.

**Marilyn:** Similar to Kim, my department chair initially encouraged me to apply for the SPDA fellowship, and reading about the requirements of the program I thought it sounded like it would work well for me; I can be a procrastinator and prefer to work with deadlines. Grant writing on my own would be at my own pace, and I thought I might not submit grants as expeditiously as I might if I had strict deadlines to follow. Having to submit a list of goals updated every 90 days to the SPDA administrator appealed to me for this reason - it would encourage me to make new goals as well as to assess my progress.

**Julie:** I applied to be a SPDA Fellow because I wanted to have a home base of sorts in the University. I wanted a niche. Because very few members of the English department faculty write
grants, I figured that moving into that arena would help me carve out a name for myself. I like the idea of being the person in the department who knows a bit about grants and grant writing. I can be a specialist among my colleagues.

_Gardiner:_ I applied at the encouragement of my Division Director, who thought I was a good match for the criteria. Grant writing has been an unknown to me and I don’t know the territory, the language, the rules, or the people, so I thought this program would de-mystify the process and help me to master one of the skills of an effective faculty member.

The Importance of the SPDA Cohort

Moving groups of fellows through the program as a unified cohort was one of the primary objectives of the SPARC Office when they developed the SPDA Program. On the whole, the fellows find this tactic beneficial in many ways and feel it is a very strong, positive component of the SPDA Program.

_Heng-Yu:_ I think that the best part of being in a cohort is sharing ideas with each other. I no longer feel that I have to pursue grant writing alone and it’s great that I have others to share ideas with. All of us are assistant professors from different departments and are relatively new to our university. Some grants emphasize a spirit of cooperation among people from different fields. By knowing these people as cohorts, I can easily make connections and get to know other people through them. I feel like I belong to a community and not learning alone anymore.

_Marilyn:_ I agree with Heng-Yu, talking to other members of this cohort has given me new ideas about the types of grants I can apply for, ideas that I would not have generated independently. Also, as part of our requirements, we must review each other’s grants. I know this will be very instructive, on both sides. Having non-biologists read my grants will greatly improve their clarity and flow. Reading other grants will give me great ideas about how grants can be written and will give me new ideas that should improve my own grants.

_Gardiner:_ The cohort has started to become a support group and tour group for the new culture of grant writing. The support comes from all of us being in a similar place in our careers and especially with grant writing, from each of us encouraging the others, and from the Grants Office research administrators through conveying a can-do attitude to us.

_Kim:_ It is nice to be able to share concerns and questions with the other SPDA Fellows. Also, our participation lets the SPARC office know that we are actively pursuing funds, and that we are trying to be conscientious faculty members. This simply increases their willingness to help us because the SPARC office wants to see the faculty succeed.

_Julie:_ Right now we see each other relatively often through our SPDA Fellowship, but I imagine that our relationships will develop and extend beyond our two years together. This is because we will struggle through many of the same issues as our careers evolve. By developing relationships now, we have a group of people we can trust as tenure looms closer.

_Heng-Yu:_ I am thrilled to be part of the SPDA fellowship. I want to learn how to be a “great” grant seeker, grant reviewer, and grant getter. I want to be able to find out where to find more grant funding opportunities that relate to Educational Technology. I enjoy learning why some proposals get funded while others do not. I am especially interested in studying how people get multimillion dollar grants, the grant structures, which methodologies they used, and how they structured their proposals.

_Marilyn:_ One unexpected benefit that is emerging from my participation in this program is a closer relationship with our sponsored projects office. All grants must go through this office, so knowing the personnel there, how they work, and how the system works is quite valuable.

_Julie:_ Being SPDA Fellows allows us to get to know the Grants Office research administra-
tors. Building this relationship is vital for future proposals and proposal ideas. It also gives us two years where we are perceived as learners. The Grants Office research administrators act as our mentors (which they are) and are partially responsible for our success. My experience so far has been positive because the research administrators understand that I am new and still learning.

Robin: I also am learning about how the Grants Office works at our university. The politics, who does what, who to go to for what information, what I need and what they can provide.

The Significance of Grant Writing to New Faculty Members

In this section, the fellows discuss their views on writing grant proposals from the position of young faculty trying to earn tenure. Vastly different personal and departmental expectations regarding grant proposal writing are revealed.

Robin: Thinking about grant writing as a new faculty member is relatively daunting. The grants I knew about coming into the program were 50-page grants – rather intimidating to me when sitting down to write. I now appreciate that I need to develop a reputation in the field of special education before going for the “big” grants. Having others that I trust to help me review my grants before I send them in will be helpful. I’m more optimistic about writing now. I just have to be more disciplined.

Julie: I never considered grant writing until I took this faculty position. Grant writing was never discussed during my graduate student days. We focused on getting articles published and presenting papers at conferences. Grant writing just never entered the picture for me or for many graduate students I knew in English programs throughout the University. So, as a new faculty member thinking about grant writing, I am actually an anomaly. I am so new to it I feel like a student all over again. And I am! That is probably one of the things I like about it most. What worries me is actually getting the grants—when will I ever find the time to do all the exciting ideas I keep writing about in grant proposals?

Rob: Grant writing in the department of mathematical sciences is not necessarily a critical factor for being a successful member of the department. Like English, in the field of mathematics, scholarly activity often is based on publications and much of the research in mathematics is theoretical in nature that needs little external funding. Mathematics education is entirely different. To conduct research in mathematics education, data must be collected and analyzed, which often requires video or audio taping and other equipment. Additionally, many mathematics education projects involve curriculum materials or instructional and assessment tools that need to be purchased for the participating schools. All of this requires funding.

Kim: Being a new faculty member in the chemistry department, I am expected to write proposals and bring in research dollars to fund both undergraduate and graduate research programs. But the reason I want to write more and better grant proposals is that a responsible member of the faculty should want to do what is best for the students. Chemistry is a field that requires expensive instrumentation and funds for consumable supplies for research. In order for the students to have the best possible educational experience, they must be given the opportunity to participate in research that is of current interest and uses modern instrumentation. The only way to offer an ongoing and sustained research program is to seek external funding from granting agencies.

Marilyn: Similar to Kim, grant writing is now considered an expectation. The long-term trend in biology has been away from teaching-based faculty with little or no expectation of research, to new hires of research-oriented faculty with a strong research agenda. I fall into the latter category. Along with the expectation of productive research (to include publications and advising graduate students) I am expected to apply for external grants. No grant...
For the most part, one cannot conduct research without funds, so the two must go hand in hand. However, an emphasis on grantsmanship is not new to me, it started in graduate school where I applied for, oh, probably a dozen small grants to fund my dissertation research. In addition, despite rather heavy teaching loads, the faculty in our department has been remarkably successful at receiving external grants, so a pretty high bar has been set.

Julie: Wow! I cannot imagine the pressure Marilyn feels. I, on the other hand, do not come from a discipline that even thinks about grants. Being in English Education affords me many opportunities in grant writing because literacy development is a heavily funded enterprise. Others in the English department do not have these kinds of grant writing avenues, so many faculty members do not write a single grant in their career.

**Where is the SPDA Going to Lead?**

In this section Fellows contemplate where participation in the SPDA Program will lead them. On the whole, the fellows have high expectations that the Program will improve their grant proposal writing skills and their ability to successfully compete for grants.

Marilyn: Frankly, my ultimate goal is to get tenure. In my department, it is pretty well understood that if I haven’t at least applied for, and more likely if I haven’t gotten a large external research grant, tenure is a no-go for me. When this two-year fellowship is done I will have submitted two grant proposals, and this will put me firmly on the road to a successful tenure package. On a more proximate level, I cannot continue my research for long without a research grant. I was given start up funds to equip my laboratory, but to gather data, complete experiments, train and fund graduate students and publish and present my research, I need money. So a research grant is a necessity to me, and this fellowship will help me get there more quickly, in my opinion, than if I was not a part of the SPDA. I am really excited about this prospect.

Rob: If one of the grants happens to be successful, then I think in grant writing success follows success. In fact, it seems like grant writing is a vicious cycle similar to the cycle of poverty: Granting institutions do not want to award novices money because they have not shown a record of success, but money is needed in order to become successful. Whether or not I am successful in obtaining grant from the SPDA Program, the experience of writing the grants will be used in the future. I think being part of the cohort and learning about other colleagues’ goals may lead to collaborative grant writing as well. As a mathematics educator, I can foresee working with several of the members of the cohort in research and teaching programs funded by grants. At the very least, the experience of working with the UNC faculty has been a great opportunity to network.

Heng-Yu: Personally, I enjoy the opportunities to get to know other SPDA Fellows who are from different disciplines and I find their research interesting. I can also see myself working with some of them in the near future to pursue some external grants. For example, if there was a grant proposal related to English writing and Technology then I could contact Julie, and if a grant proposal was related to math and technology then I could contact Rob, etc. Even though this is only my first semester as a SPDA Fellow, I feel that I made many friends and made more connections with people outside of my own discipline.

Gardiner: I believe the SPDA will help me to take a chance, a risk, and just begin to try. It will develop my confidence over time and link me to the campus and national resources I need to be a successful grant writer – building my grant writing self-esteem, so to speak. I am encouraged by the personal support of our SPARC staff here, and see the genuine care they have for us as fellows. This will help our entire group learn the skills of grant writing.

Julie: I’m not sure I have any idea where SPDA will lead me, but that is one of the reasons why I like it. I find a lot of value in getting to know other faculty in different departments and a wider view of the University in general. In terms of my future, I think that being an
SPDA Fellow will also give me some grant writing ethos in the English department. Already I have people ask me to help them with grants, grant ideas, and I’ve been given the unofficial title of “grant guru.” That’s a bit strange, I admit it, but I do like knowing that the faculty value this grant writing track I want to take in my career.

Robin: I plan to write grant proposals so that I can fund my desire to work in schools. This will then lead me to be able to write texts, articles and report relevant research related to my funded grants.

Kim: I hope the SPDA Fellows programs leads to lasting relationships across the university community. I have already gotten to know some truly wonderful people through the program and have contacts in departments other than my own for help with grant proposal writing and other issues common to new faculty that may arise. I hope it will lead to possible collaborations with other Fellows.

Conclusion

Overall, the seven SPDA Fellows are actively pursuing grant funding and are enhancing their skills in writing successful grant proposals. With the support of each other, the SPARC office, and each of their departmental chairs, faculty, and deans, the Fellows are becoming successful teacher-scholars continuing to provide students with quality educational experiences in the classroom, while bringing in additional grant funding for research projects. The Fellows feel that the program has been helpful to them so far and expect to take advantage of the opportunities that the SPARC Office provides in the future. Additional support (e.g., time, money, help with grant proposals) provided by the SPARC Office and the University allows each Fellow time to perform preliminary research and write proposals as well as the opportunity to develop as teacher-scholars. The relationships established among the Fellows will continue throughout their careers, laying the foundation for interdepartmental collaborations and support.

Appendix A

SPONSORED PROJECT DEVELOPMENT AWARD PROGRAM
APPLICATION COVER PAGE

Applicant Agreement:
Should this application result in the award of an SPDA fellowship, I agree to participate fully in the program by:

• Attending a day-long proposal writing workshop on April 18, 2003.
• Participating in at least six additional learning activities selected from a roster of grantsmanship workshops and seminars that will be sponsored by SPARC throughout the program period.
• Developing a written self-contract to include research and grantwriting goals and objectives for five years, for the 24 month fellowship period, and for the ensuing 90 day period. Reviewing and submitting a new 90 day contract every three months during the program period.
• Developing a mentoring relationship with another faculty or staff member at UNC in order to establish a network of key colleagues, and working with the mentor throughout the program period to strengthen grantsmanship skills.
Appendix A (cont.)

- Attending at least eight of ten group luncheon meetings that will be scheduled throughout the program period to discuss different areas of grantsmanship, brainstorm research plans, and present progress in achieving program goals with other program participants. The first of these meetings will be held May 2, 2003.

- Attending the Annual Distinguished Scholar Banquet during both years of the program.

- Submitting two proposals of at least $50,000 each (one of which must be to a federal agency) before the first of April, 2005.

- If those proposals are not funded, revising and resubmitting for the next deadline or to a different sponsor (this is likely to occur after the program period has ended in some cases).

- Developing a Quality Review Team to review my proposals before the proposal deadline date, allowing adequate time to revise the proposal according to the review team’s comments, if needed, prior to submission.

- Participating on Quality Review Teams for at least two other SPDA fellows, reviewing one of their proposals prior to submission.

- Submitting interim progress reports on 12/1/03 and 10/1/04, and a final report on 4/1/05 to the Dean of the Graduate School and Associate Vice President for Research.

Applicant Signature ___________________________ Date ______________

Administrative Agreement:
Should this applicant be selected for a fellowship award, I will support the applicant’s participation in the 2004 SPDA Program by agreeing to:

- Allow time for the participant to attend the required program sessions (workshops, meetings, trips);

- Allow a one-course release for the participant during fall semester 2003, the actual cost for replacement (salary and fringe benefits) up to $3,000 to be paid by SPARC;

- Give the participant’s work in the program appropriate consideration in promotion, tenure, and salary increase decisions; and

- Select a mentor with the participant, who is knowledgeable of the participant’s proposed work and is willing to devote time to help the participant during the two-year program period.

Department Chair/Unit Director ___________________________ Date ______________

College Dean/Admin. Equivalent ___________________________ Date ______________
Subcontracting Primer: The ABCs of Agreements Between Collaborators

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Abstract
Even before all the corporate scandals and charges of corporate accounting indiscretions and manipulations, members of Congress were becoming increasingly concerned about the amount of attention federal agencies were paying to grant recipients. Congressional leaders were beginning to ask the federal funding agencies what procedures they were employing to ensure grant recipients were complying with federal regulations and the Office of Management and Budget (OMB) circular requirements. This concern has lead to an increased focus on the handling of subcontracts and how to ensure subrecipients are handling federal funds in a fiscally responsible and compliant manner. Consequently, audit firms are focusing more attention on how lead institutions are monitoring subrecipients when conducting the lead institution’s A-133 audit. This paper seeks to describe how to pass down and oversee compliance with essential responsibilities of subcontract administration.

Introduction
Collaborations among researchers of multiple institutions are becoming an essential element in a growing number of research projects, and oversight of subcontract relationships is under increasing scrutiny by auditors and federal awarding agencies. The agreements that accommodate these collaborations are coming under increased scrutiny by the federal government, and the 2003 supplement to OMB Circular A-133 (Part 3, item M) describes subrecipient monitoring as one of the core compliance requirements that applies to most federal assistance programs. According to the Federal Grants Management Handbook, this section of the 2003 supplement to OMB Circular A-133, includes audit objective, suggested audit procedures as well as an overview of subrecipient monitoring with references to specific circulars and relevant citations pertaining to subrecipient monitoring. A task force working on implementation of the Federal Financial Assistance Management Improvement Act (P.L. 106-107) will be evaluating whether the federal government needs to issue even more guidance on subrecipient monitoring. (2003)
Knowing how to manage collaborations properly from a research administrator’s perspective is an important grants management function. While performing this function, a research administrator must take care that the contractual instrument not overshadow the function it is designed to accommodate. Before designing an agreement the research administrator must know the function of the agreement: its purpose, what it should do, and what it should not do.

Research collaborations that involve subrecipient agreements have principal investigators (PI) in both the lead and subrecipient institutions. Frequently the PI at the subrecipient institution is the direct recipient of federal funds on other projects and therefore will not be a neophyte in the responsible management of federal funds. Occasionally, however, the subrecipient PI is inexperienced at grants management.

The success or failure of the collaboration depends not on the subcontract agreement but on the relationship that exists between the collaborators. If collaboration fails, it is usually due to the breakdown in the relationship between the PI’s. During the performance period, the role of the research administrator should not be that of institutional warden, and the agreement should be one that is flexible enough to accommodate the needs of the project and the researchers while ensuring that all compliance and award requirements are met.

The subrecipient agreement is the institutional framework that provides structure to the professional relationship of the collaborating researchers. The agreement should be written in a way that will protect the grantee institution, flow down the terms and conditions of the prime award, and allow the PI to concentrate on the research relationship with collaborators and the project at hand. This paper will focus on the essential elements of a subrecipient agreement to ensure compliance with OMB Circular A-133. Two appendices have been included – Appendix A is a listing of some of the public policy requirements that federal award recipients are required to adhere to and must be “flowed down” to subrecipients and Appendix B lists the various types of subrecipients and the Office of Management cost circular that applies to them.

Vendor or Subrecipient?

The first step is to determine whether the relationship is that of a subrecipient or a vendor. OMB Circular A-133, Subpart A, Section 105 (Audits of Institutions of Higher Education) and OMB Circular A-110 (Uniform Administrative Requirements for Institutions of Higher Education, Hospitals and Other Non-Profit Organizations) contain definitions of vendor and subrecipient. Vendors, although providing an essential service or product to a program, provide the same service or product as a routine part of their daily business and are not subject to OMB Circular A-133 or the compliance requirements of the award terms and conditions. Vendors generally supply goods and services that are necessary to the completion of a project but are not part of a cooperative programmatic effort. Subrecipients are usually sole source contributors (for example: universities, research institutes, hospitals employing professionals with unique experience and skills) who are part of the programmatic decision-making process and whose performance is measured against the program objectives. Subrecipients are subject to OMB Circular A-133 requirements (except foreign entities or institutions with less than $500,000/year in federal expenditures) and must adhere to compliance requirements. A subcontract creates no direct contractual relationship between the subrecipient and the awarding agency. The relationship established by the subcontract agreement (also called subrecipient agreement, subgrant, subaward) is between the lead institution and the subrecipient and is a collaborative venture to bring to successful completion a project for which funding has been secured.

Reaching an Agreement

If addition of a subcontract becomes necessary after the award is made, the awarding agency may require prior approval before they will issue the subcontract. In this case, the best is always to check with the agency guidelines. When a planned subcontract is part of the approved proposal, approval of the subcontract is part of the award.

Before issuing a subcontract under the prime award, the lead institution should require that the
The subcontract agreement also serves to protect both institutions by making clear the subrecipient's responsibilities. A checklist that the subrecipient must complete and submit as part of the subcontract proposal package may prove helpful. The lead institution is responsible for the subrecipient’s adherence to the terms of the prime agreement. To assist the researchers at the Institute of Ecosystem Studies (IES), a document outlining the procedures that must be followed has been compiled and is available at http://www.ecostudies.org/grants.html.

A clear understanding of the respective roles and compliance with the terms and conditions of the award by PI’s at both institutions are vital to the success of the project. The subcontracting agreement lays the groundwork for the collaborative arrangement between the institutions. Therefore, a well-structured and inclusive document is necessary. The agreement must clearly state the conditions of the relationship and flow down the necessary terms and conditions of the prime award. OMB Circular A-133 § 400(D) lists the obligations that pass-through entities must meet for subrecipients. The subrecipient agreement should include these obligations:

1. **Identifying information** – The pass-through entity must identify the federal award and give the subrecipient the Catalog of Federal Domestic Assistance (CFDA) number and title, the name of the federal awarding agency, and the award number. If this information is not readily available to the pass-through entity, it should provide the subrecipient with all available information that best describes the federal award;
2. **Statement of work** – work stated in the proposal that the subrecipient will be responsible for completing. Subrecipients should state the work they will perform and the goals they hope to achieve;
3. **Project Direction – Key Personnel** – Name the PIs at both institutions. When referring to the PI at the subrecipient organization, include the statement “who is essential to the project”;  
4. **Duration of the Agreement** – The start and end date of award cannot exceed the timeframe in the prime award;
5. **Estimated Cost** – The amount should not exceed the amount stated in the subrecipient proposed budget, which should be attached as an appendix to the agreement;
6. **Allowable Costs** – cite applicable OMB circular reference (see Appendix B). The pass-through agency must monitor the subrecipient’s expenses to ensure the funds are being used for authorized purposes;
7. **Payment** – address, format, and timing of invoices; invoices should itemize expenses and include period covered, expenses for the period, and itemized cumulative expenses;
8. **Audit and Record Retainage Requirements** – prime agency and pass-through agency must have permission to access the financial records of the subrecipient. State the period of time the records must be kept. The pass-through entity must ensure that subrecipients expending $500,000 or more during the subrecipient’s fiscal year have met the audit requirements for that year. If warranted in the audit findings of the subrecipient, and it is necessary for the pass-through entity to adjust its accounting reports. If warranted the pass-through entity must follow up to ensure that the subrecipient is taking corrective action in an appropriate and timely manner.
9. **Changes in Objectives, Scope, or Personnel Reference** – how any proposed changes should be handled and what permissions must be obtained for changes;
10. **Termination Clause** – conditions and terms for dissolution of agreement;
11. **Reports and Deliverables Due** – state what
is required and when due. The pass-through entity must monitor the subrecipient to make sure that the stated goals of the project are being met. Requiring the subrecipient’s program report to be due a month before the pass-through institution’s report to the agency so it can be incorporated into the progress report to the prime agency is prudent;

12. Additional Terms And Conditions – specific to agency requirements and the terms and conditions of the award. Provide the subrecipient with compliance requirements (see Appendix A) and attach the agency terms and conditions to the agreement;

13. Precedence Reference – determine which takes precedence if subrecipient agreement and prime award are in conflict;

14. Indemnification (if allowable) – because of state laws, some state universities do not permit indemnification but usually have language to which they can agree;

15. Rights in Data and Material – specify the right for both prime and lead agency to use material royalty-free;

16. Publication Clause – should include publication expectations; co-authorship stipulations (if any) and Stevens Amendment provisions (see Appendix A);

17. Independent Contractor Clause – include a statement that the subrecipient is an independent contractor;

18. Subcontracting Clause – no third party subcontract is allowed without lead institution approval;

19. General Release Clause – statement that payment of final invoices releases further claims of recipient;

20. Use of Name Clause – limitations on the use of the name of either institution; and

21. Complete Agreement Clause – this agreement is complete and supercedes previous agreements.

Specific situations may eliminate some clauses or dictate additional clauses. For example Institutional Animal Care and Use Committee approval date and Animal Welfare Assurance Number and Human Subject Exemption Number or Institutional Review Board Approval Date and Assurance of Compliance Number can be added, if applicable. The authorized official of both institutions must sign and date this agreement. In addition, the agreement should include the prime agreement number, the subrecipient’s Dun & Bradstreet Universal Numbering System (DUNS) number, the contact information for both institutions and their respective addresses. Institutions without a DUNS number may go to http://www.dnb.com/US/duns_update/index .html to acquire one.

The subrecipient also has the following responsibilities.

1. Administering the award in compliance with the terms and conditions of the award and the applicable circulars;

2. Having adequate internal controls to manage the subcontract;

3. Ensuring that all the terms and conditions of the award are carried out;

4. Requesting prior approval from the pass-through (lead) entity (not the granting agency), when necessary;

5. Providing pass-through (lead) entity with copies of A-133 report, when applicable, or informing pass-through (lead) entity when there are no management findings. If requested by the pass-through entity, the subrecipient is required to send the A-133 report even if there are no management findings;

6. Keeping current on all changes in procedures or requirements and advising the principal investigator of changes.

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1 OMB Circular A-133 §.320 (c) (e) (f) Subrecipients shall submit to each pass-through entity one copy of the reporting package... when the schedule of findings and questioned costs disclosed audit findings relating the Federal awards that the pass-through entity provided... (2)...the subrecipient shall provide written notification to the pass-through entity that: an audit of the subrecipient was conducted in accordance with this part... the schedule of findings and questioned costs disclosed no audit findings related to the Federal award(s) that the pass-through entity provided; and, the summary schedule of prior audit findings did not report on the status of any audit findings relating to the Federal award(s) that the pass-through entity provided... (f) In response to requests by a Federal agency or pass-through entity, auditees shall submit the appropriate copies of the reporting package...
In an attempt to clarify the compliance responsibilities of pass-through entities, the annual compliance supplement to OMB Circular A-133 contains clarifications of the responsibilities the pass-through entity has for monitoring a subrecipient’s compliance. The 2003 annual supplement applies to audits conducted on fiscal years beginning after 30 June 2003. The 2003 supplement is available on the Office of Management and Budget website at http://www.whitehouse.gov/omb/grants/grants_circulars.html.

Once the agreement is in place, the pass-through or lead entity’s most important role is to monitor the subrecipient. Many lead institutions fall short of this responsibility because they do not fully understand their role and do not document their monitoring activities. Before entering into a subcontractual relationship, the lead institution should establish a checklist of monitoring activities. A checklist serves as a ready reference of all the pertinent information that the pass-through agency needs to have for the subrecipient. It is also an aide memoire that all the information necessary for subrecipient monitoring has been received and is up-to-date. This checklist should include institution name, DUNS number, contact person, auditor name, A-133 report request and receipt, agreement number, CFDA number, federal agency, amount of the award, whether the research project involves vertebrate animals or human subjects. If applicable, note the Institutional Animal Care and Use Committee approval date and Animal Welfare Assurance Number and Human Subject Exemption Number or Institutional Review Board Approval Date and Assurance of Compliance Number. Recording this information on the checklist can be very helpful during an A-133 audit and will help the pass-through entity make sure that the subrecipient’s applicable assurances are current.

Database programs can be a powerful as well as a very useful tool for capturing monitoring information. A carefully designed database can be the central, electronic repository that allows the user to organize information into tables that can be linked and queried to generate reports that are both functional and timely. For example, the reports can be designed to serve as a reminder that assurances are due to expire and when, that A-133 reports have or have not been received or can be designed to contain subrecipient information requested by the auditors.

The lead institution should also maintain a file for each subrecipient that contains all correspondence including relevant e-mails and notations of telephone conversations.

Finally, the lead institution should review the invoices submitted by the subrecipient to ascertain that requested reimbursements are for allowable expenses within the performance period of the agreement, the amount of the agreement has not been exceeded, and the invoices contain no mathematical errors. Many institutions require that the invoices include a statement signed by the person responsible for issuing the invoice verifying the accuracy of the expenses. Before making payment, the lead institution’s PI should verify that the work has been performed and both the PI and a staff member responsible for overseeing the project’s expenses should approve the invoice.

**Conclusion**

Taking the time initially to construct a clear and concise agreement and establishing monitoring procedures are essential to ensuring that institutions are in compliance with OMB regulations and agency terms and conditions and will help cement the collaborative relationship between the two institutions. Smooth administrative relationships facilitate productive collaborations among the professionals involved. It is also important to have reference tools such as The Thompson Publishing Group’s *Federal Grants Management Handbook* or The National Association of Colleges and University Business Officers’ *A Guide to Managing Federal Grants for Colleges and Universities* and a current version of OMB Circular A-133.
References


Appendix A

Some Examples of Public Policy Requirements

• Davis-Bacon Act, P.L. 86-624 & P.L. 88-349; 40 USC 276. FAR implementation at 52.222-6 – sets wage rate for laborers and construction workers on federal projects.

• Title VI of the Civil Rights Act of 1964 – prohibits discrimination based on race, color or national origin.

• Freedom of Information Act, 5 USC 522, as amended and implemented in each federal agency’s Code of Federal Regulation section – grants public access to federal records.

• Fly American Act, International Air Transportation Fair Competitive Practices Act of 1974, Section 5 and implemented in FAR 52.247-63 – requires travelers using federal funds to use American owned airlines whenever possible.

• Stevens Amendment, Defense Appropriations Act of 1986 (P.L. 100-463); Department of Labor, Health and Human Services, and Related Agencies Appropriations Act of 1990 and 1991 (P.L. 101-166 and 101-517, Section 511) – requires grantees to give credit to funding agencies in all publications.

• Drug Free Workplace Act of 1988 (part of P.L. 100-690,Title V, Subtitle D: 41 USC 701, et seq.) – requires at a minimum that an institution develop a workplace policy and distribute it to all employees and students.

• Anti-Kickback Act of 1986, FAR 52.203-7 – states it is unlawful for subrecipients to make payments and for subcontractors to accept payments for the purpose of obtaining or rewarding favorable treatment in connection with either a subcontract or contract relating to prime award.

• Lobbying Disclosure Act of 1995 (P.L. 04-65) – requires the reporting of lobbying efforts that are aimed at Congress and the Executive branch of government.

Appendix A cont. next page
Appendix A (cont.)

• The Clean Air Act and the Federal Water Pollution Control Act. Required by the Clean Air Act (42 USC 7401 et seq.), the Federal Water Pollution Control Act (33 USC 1251 et seq.), Executive Order 11738, 10 September 1973 (38 FR 25161), 12 September 1973 and the Environmental Protection Agency regulations at 40 CFR, Part 15 – must certify if facilities to be used in the proposed work are listed by the Environmental Protection Agency (EPA) as violating facilities and promise to give notice if informed by the EPA that facilities have come under consideration for listing.

• The Patriot Act, 25 October 2001,Subtitle B Section 411 – 416 Enhanced Immigration Provisions. This act limits the research activities of international students and other “restricted persons” and the possible creation of a new category of restricted information designated as “sensitive but unclassified.” Available at http://www.eff.org/Privacy/Surveillance/Terrorism_militias/20011025_hr3162_usa_patriot_bill.html.

• The Bioterrorism Preparedness and Response Act, Public Health Security and Bioterrorism Preparedness Act of 2002 - Public Law 107-877 - July 12, 2002 - includes a list of selected agents (42 CFR72, Appendix A) that must be reported to the federal government if used in a grantee institution. The new law requires an institution to register with the CDC if it possesses these infectious agents, toxins, and genetic elements. The list is available at http://www.fda.gov/oc/bioterrorism/bioact.html.

Appendix B

FEDERAL COST PRINCIPLES APPLICABLE TO GRANTS AND COOPERATIVE AGREEMENTS

<table>
<thead>
<tr>
<th>TYPE OF (SUB) RECIPIENT</th>
<th>COST PRINCIPLE</th>
</tr>
</thead>
<tbody>
<tr>
<td>College and University</td>
<td>OMB Circular A-21 – Cost Principles for Educational Institutions</td>
</tr>
<tr>
<td>State, Local or Indian Tribal Government</td>
<td>OMB Circular A-87 – Cost Principles for State, Local and Indian Tribal Governments</td>
</tr>
<tr>
<td>Non-Profit Organization</td>
<td>OMB Circular A-122 – Cost Principles for Non-Profit Organizations</td>
</tr>
<tr>
<td>Hospitals</td>
<td>DHHS Regulation 45CFR Part 74, Appendix E</td>
</tr>
<tr>
<td>For Profit Organizations</td>
<td>FAR 48 CFR Part 31</td>
</tr>
</tbody>
</table>
Commentary

Two Roads Converge: The Challenge of Human Subject Protections In the Forensic DNA Research Context

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Abstract

A variety of concerns emerge when considering the ethical protection of human subjects and the complex issues surrounding privacy and confidentiality in DNA profiling. This paper spotlights these concerns by examining (a) the science of DNA analysis and the identifiable nature of forensic DNA samples; (b) the ethical challenges forensic DNA samples pose to privacy, confidentiality, and respect for persons within human research; and (c) the potential problem of exemption for DNA samples under 45 CFR 46.101.b. These issues point to the essential requirement that scientific progress must be tempered by the ethical parameters that maintain the human face of research. This convergence of the two roads of ethical standards and research advancement poses an unavoidable challenge to research executives whose leadership must promote research production but never at the expense of human protections.

Authors’ Note: This article was adapted from Vaughan Caines, Confidentiality, Privacy and Respect for Persons as Challenge-Horizons in Forensic DNA Research, a paper published in the 2003 Symposium Proceedings for the Annual Meeting of the Society of Research Administrators International, Pittsburgh, PA. 19-22 October 2003. Disclaimer: The opinions in this paper are those of the authors and do not reflect the official policy of the State of New Hampshire Department of Health and Human Services, the Department of the Navy, the Department of Defense, or the United States Government. Contact: Mr. Vaughan Caines, Forensic Toxicologist, State of New Hampshire Public Health Laboratories, 6 Hazen Drive, Concord, New Hampshire 03301. Email: vcaines@dhhs.state.nh.us.
Introduction: 
A Contemporary Challenge to the Rights and Welfare of Human Subjects in Research

History is replete with examples of the propensity of humankind to throw caution to the wind when searching for and learning about the untapped potential of scientific discovery in research. Sometimes this lack of caution has been the cause of tragedy. Two major instances immediately spring to mind: The Holocaust of World War II and the Tuskegee Syphilis Experiments conducted by the United States Public Health Service on poor disadvantaged African-Americans in the period between 1932 and 1972. Both disregarded the well being and rights of the individuals that were involved in the respective experiments. Some conjecture today that we may be on the cusp of a horrific déjà vu.

We live in the information age. Knowledge and information are power. Important information such as characteristics, disease, and personality is personal. Much of this information is locked inside of our DNA. Advances in modern science have provided keys that can unlock this mysterious Pandora’s Box. Does the unlocking of our personal characteristics from our DNA pose dangers in human research?

Consider the following scenario which may not be that far fetched. Imagine going out for a meal and having a glass of water; then someone comes along, takes the glass, and through a simple manipulation, removes thousands of cells that you left behind. The DNA is extracted from the cells, copied, and then profiled, exposing genetic information that was unknown to you. Is this possible at the present? Yes. Is this happening in today’s society? Unknown—for the moment! There would be nothing you or anyone could do about this situation. You did not consent to the testing, nor did you have a say as to who sees your information.

The gleaning of information from DNA samples occurs daily around the world in different settings. Two of those settings involve research and diagnostic applications. Typically these applications are looking for hereditary information (paternity or lineage) and genetic history (predisposition to disease or disorders). Law enforcement/forensic science uses a third application in which DNA information generates a genetic profile to serve as an identification tool. The profile is defined and stored in a database, and a sample is then stored in a DNA repository for future analysis at the discretion of a law enforcement agency. Could this sample be considered anonymous if used in a forensic DNA research study? The use of DNA in forensic science application makes an individual’s DNA code a unique identifier. When DNA is used post-factum for research purposes, what ethical challenges are emerging for human subject protections and specifically what rights and privileges must one relinquish or be required to relinquish as a prisoner?

This question provides the essential energy behind the discussion to follow. To approach this question it will be necessary to focus on three areas: 1) The identifiable nature of forensic DNA samples; 2) the inviolability of privacy, confidentiality, and informed consent in human research; and 3) the question of exemption under 45 CFR 46.101.b.

Ultimately, in this discussion what emergent challenges exist for research administrators and the role of leadership we are asked to provide for our respective communities and institutions?

Focus on Science: 
The Identifiable Nature of Forensic DNA Samples

The first step in the exploration of the present discussion must be an examination of the identifiable nature of DNA samples. DNA profiling is a process that begins when a minute sample of genetic material - DNA - is taken from human tissue. The process ends when the sample is given a computerized numeric value in the form of a bar code and stored in a database. DNA can be collected from individuals using a variety of samples including blood, semen, saliva, hair root, or bone. The technique that is most favorable due to its non-invasive nature is the mouth swab. Once the sample is collected, the DNA must be processed or profiled. (Rudin & Inman, 2001)

Taking a DNA profile involves analyzing it at 13 different locations (also referred to as loci) from various parts of the molecule. Statistically, no
two people (except identical twins) are likely to have the same profile. This would seem to make DNA a unique personal identifier.

DNA profiling or analysis is a complicated process and is carried out in sequential steps. The generated profile is stored in the appropriate database. Identification of a particular individual is possible by the profile and the sample because the profile is specific to individuals much like a fingerprint or another unique human identifier. However, the question is what are the implications of DNA profiling and the storage of samples from which they have been harvested?

On the positive side, the world of jurisprudence has benefited greatly from the unique abilities of DNA profiles. Examples of such benefits are the rapid and absolute elimination of innocent suspects, culminating in the speedy identification of offenders with a very high degree of certainty. The reliability of evidence produced in court makes for better administration of justice, which leads to an increased public confidence in the criminal justice system. This potentially has a deterrent effect on offenders, which could lead to a concomitant decrease in crime, thus increasing cost-effectiveness in terms of investigation time saved. But are the results totally positive? Does this technology have any negative and potentially destructive implications? One place to examine this is the world of human subject research.

**Focus on Ethics: Privacy, Confidentiality, and Informed Consent as Central to Human Subject Protections**

Significant and highly charged, popular discussions suggest that DNA profiling poses great difficulties in the areas of human rights and personal freedoms (American Civil Liberties Union, 2002; Human Research Protection Program, 1996; National DNA Data Bank Advisory Committee, 2002; Rooker, 2000; Rothstein, n.d.; Wines, 2002). Such difficulties would be especially important for scientific research and the demands of ethical leadership for research administrators. To explore these facets, reflecting upon the ethical and regulatory guidance concerning privacy, confidentiality, and informed consent relative to human research is important.

**The Nuremberg Code**

The Nuremberg Code established ethical, medical and scientific norms for human research protection in response to the atrocities of the Nazi Holocaust during World War II. The code is comprised of ten separate points. Summarized, the Code articulated that the voluntary informed consent of the human subject was absolutely essential to protect the rights of the individual. The Code recognized that unnecessary pain and suffering must be avoided and that the benefits of research to individuals must outweigh potential risks. The Code became the foundation for later principles and regulations that have since guided investigators and provide contemporary parameters for the conduct of human subject research. While the Code does not specifically address privacy and confidentiality per se, its concern for the protection of human rights clearly is predicated upon concepts of individual human freedoms from which privacy and confidentiality necessarily arise.

**The Belmont Report**

In the United States the central hub of human research protections is The Belmont Report of 1979. The objective of the Report was to provide the philosophical and ethical framework for the protection of human subjects in research regardless of discipline. The Report articulated three ethical foundations and the application of these principles in the conduct of human subject research.

1. **Respect for persons**

   This principle addresses the need to protect the autonomy of individuals and to provide special protections for those who have diminished autonomy.

2. **Beneficence**

   This principle addresses the need to protect the wellbeing of human subjects through a careful balancing of all risks and benefits
such that risks are minimized and benefits are maximized.

3. Justice

This principle requires the equitable selection of research subjects and the equal distribution of risks and benefits.

The Belmont Report brings into sharp focus the practice of these three principles when it addresses the needs for the process and procedures of informed consent. The Report requires that informed consent provide complete information in a way that can be fully comprehended by research subjects while guaranteeing they are free from all forms of coercion. The Belmont Report provides the foundation upon which the concepts of privacy, confidentiality and informed consent are shaped in The Common Rule.

**45 CFR 46**
*(The Common Rule)*

45 CFR 46, first adopted in 1974 by the then-Department of Health, Education, and Welfare as its policy for the protection of human subjects in research, represents today the culmination of more than forty years of development and discussion on the ethical principles, guidelines, and regulations for conducting research using human subjects. After 1991 when sixteen other federal departments adopted 45 CFR 46, it became known as The Common Rule. It established the parameters and core procedures needed for the protection of human subjects in research, such as the requirements for informed consent and the authority of Institutional Review Boards (IRB).

Of the fifteen elements of informed consent, eight are required and the other seven are at the discretion of the individual IRB. Among the required elements for informed consent is that an individual’s right to privacy and confidentiality must be secured. The purpose of the informed consent document is to provide information to the potential research subject such that the subject can make an informed decision about participating in the research project. The information given to the subject must provide sufficient information about the research, may not contain any exculpatory language such that a subject would waive legal rights. In short, an informed consent document reflects the deeper, more substantive, and more critical process of informed consent that is predicated upon an agenda of trust between research staff and the individual participant.

The language in The Common Rule on the requirements for informed consent indicates there is the chance that an individual investigator may not always have a clear and full understanding of all of the factors or issues involved in evaluating potential risks and ensuring full and complete protections. To assist, an IRB serves as a check and balance in the research process by acting as advocate for the research subject and for society at large. By protecting the rights and welfare of the research subject, an IRB champions society’s belief in the right to protection for human subjects in research, including the right to privacy and confidentiality as prescribed in the critical elements of informed consent as found in The Common Rule.

**The Health Insurance Portability and Accountability Act**

The protection of an individual’s right to privacy and confidentiality is underscored by the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Though HIPAA does not concern research exclusively, the Act does affect how protected health information should be used in research situations.

As the ethical principles for human research articulate society’s commitment to the protection of human subjects, HIPAA is intended similarly to set a high bar for the protection of an individual’s right to confidentiality and privacy in the use, storage, and transmission of protected health information. While HIPAA itself has been the source of contest and debate concerning its usefulness or even its necessity, HIPAA’s enduring significance may be in its raising up, at least on the level of intentionality, society’s need to secure complete respect for the right to privacy and confidentiality of every individual.
**Focus on the Dialectic:**
**DNA Samples, De-Identification, and Qualification for Exemption under 45 CFR 46.101.b**

A variety of concerns emerge when considering the ethical protection of human subjects and the complex issues surrounding DNA profiling and its impact upon privacy and confidentiality. Since even the most cursory overview of such concerns would be far too exhaustive for the purposes of this discussion, it will focus on consideration of the potential qualification of exemption for DNA samples under 45 CFR 46.101.b.

The overall intention of Paragraph 101 is to detail the scope and applicability of the activities that fall under the requirements for the protection of human research subjects. However paragraph 101.b allows for six categories of activities to be determined as exempt from the regulations. These six categories seem to hold in common a low risk for violations of the right of an individual to privacy and confidentiality. Among the categories for exemption is the use of pathological specimens and diagnostic samples if they are publicly available and cannot be linked back to the individual.

In the light of the discussion of the second section in this paper, the question is can samples collected in current or future forensic DNA research be exempt under 45 CFR 46.101.b? Since the fundamental purpose of a DNA database is to identify, thereby testifying that a DNA sample is a unique identifier, can research that involves the collection or study of DNA specimens from sources that have previously been stored in a database be considered as anonymous either theoretically or practically?

How does this issue of viewing DNA as a unique identifier impinge on the ethical principles and guidelines of The Nuremberg Code, The Belmont Report, and The Common Rule? Are these principles and regulations designed to deal with such an issue? Do they effectively consider the problems and issues that are potentially caused by such a potent and discriminating tool? Granted, a research subject’s DNA profile would have to be previously entrenched in a database for the subject’s DNA to be identified in a research study. However, is this concept closer than we realize?

Lest it be thought that this DNA database/databank issue would only affect those incarcerated or embroiled in the justice system, one should be aware that newborns today are subjected to DNA screening for a number of hereditary diseases prevalent in the general population. Once the screen is performed and the information is gleaned and stored in a database, the sample itself is stored in a repository. (Rudin & Inman 2001) Extrapolating from this simple and increasingly commonplace medical practice, one might be tempted to project a potential, however remote or seemingly implausible, promiscuous use of such DNA information or samples.

**Conclusion:**
**The Ethical Pledge of Human Research Protections And the Mission of the Research Administrator**

The potential to catalogue and maintain the genetic code of an entire population is both exciting and daunting. In one respect the incidence of certain diseases could be significantly reduced due to earlier detection. In jurisprudence the administration of justice would be more effective and efficient. In addition, the events and aftermath of 11 September 2001 would seem to make DNA profiling more palatable in the interests of personal, national, and global security against the evil of terrorism. Without question the global outpouring of concern over the events of September 11th makes extremely understandable a desire to use DNA profiling to discover the identity of any potential terrorist. (Waak 2002)

Conversely such a position is not without serious critics. Those who advocate civil liberties in the United States and around the world articulate serious concerns: Do the benefits provided by this tool outweigh its risks? Who will protect the autonomy of the individual in light of the power of this rapidly more common technology? If each person were to have his or
her DNA profile stored in a database, who would protect his or her privacy and confidentiality?

By utilizing the power of DNA analysis and profiling, a government could become the Orwellian Big Brother with the power to identify and control the individual in the interests of totalitarianism. (Waak 2002) In the end there would be not benefits and the costs would be far more than the mind can bear. Who are the guardians that can raise the implications of the potential ethical erosion that might be possible? This task is not just for the philosopher or theologian. It is also for the research administrator who oversees and shapes the fundamental act of research when it involves human subjects.

In recent years, a growing number of voices are calling attention to standards for the responsible conduct of research. These standards include much more than human research protections. Concomitantly, the role of the research administrator has evolved far beyond managerial functions and compliance oversight. Research administrators are becoming part of an unforeseen intertwining of the intrinsic need to see ethics and professional integrity as a fundamental part of research and not apart from it as an addendum or a matter of post-award inspection.

Being caught up in this new energy in the mission of research administration and being confronted by complex issues such as those of human subject protections in the light of DNA profiling, research administrators need to take seriously three important tasks. First, regardless of whether it concerns human subject protections or another aspect of the field, research administrators must know the full scope of what is expected not just legally, or for regulatory affairs, but also ethically. This requires the professional to go beyond knowing the cognitive content of regulations to appreciate their meaning, or as philosophers refer to it, their “ontology.” What is the meaning of a specific regulation? Why did it occur? Second, research administrators need to learn how to interpret and adapt ethical requirements for specific issues. Regulations are not necessarily univocal. They need to be adapted and shaped to meet the challenges of any set of circumstances in any given time and place. And third, research administrators must be ready to make major revisions and reforms to existing policies and practices to meet new understandings of ethical horizons or to meet unforeseen circumstances.

In the final analysis, research administrators have a critical function to call attention to what is emerging in the research life of an institution and the ethical impact that will follow. In this regard, the two roads of ethics and industry, of research production and research protections, meet and converge and collide in the mission of the research administrator and the fundamental act of research. The research administrator must know how to negotiate the inevitable collision and harness the ensuing energies when road meets road. We wonder which to trod; but we know—we know that, almost paradoxically and impossibly, we must follow both!

The discussion above on human research ethics and the challenge of DNA profiling bring into high relief the critical leadership of research administrators—a leadership that calls our institutions and investigators to follow the highest calling of research itself, namely the continued securing of human progress but never at the price of human freedom.
References


Protecting the Privacy, Confidentiality, Relationships, and Medical Safety of Sex Partners in Partner Notification and Management Studies

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Abstract

The practice of partner notification and management is an important public health strategy in the control of sexually transmitted diseases. There are, however, concerns related to the ethical principle of beneficence about the potential for unintended negative consequences in scientific studies of new strategies for partner notification and management. These concerns include threats to privacy and confidentiality, the potential for breakdown in relationships, and side effects of medications provided for the treatment of sex partners. We conducted computerized and manual searches and reviewed the 10 most recent published articles on studies of partner notification and management. Procedures that can be used to protect participants and their partners include a truly informed consent and authorization process, use of stringent procedures for handling study data, training clinical and research staff members and study participants, and using appropriate wording and delivery modes to reach and inform the partners. We discuss the need for a forum to exchange information on ethical considerations, reflect on the conduct of scientific studies for new strategies of public health practice, and highlight the interactions between ethical considerations and generalizability of study results. Our aim is to enhance the compatibility of scientific goals, public health practice, and ethical principles.

Author’s Note: Because the paper was nominated for a best paper award by the scientific committee for the 2003 meeting of the International Society of Research Administrators, portions of this paper were presented at the 2003 Annual Meeting of the International Society of Research Administrators, Pittsburgh, PA, October 2003. Contact Salaam Semaan, DrPH, Division of STD Prevention, Centers for Disease Control and Prevention, 1600 Clifton Road, E-02, Atlanta, GA 30333. E-mail: ssemaan@cdc.gov.
Introduction

The practice of partner notification and management, also known as contact tracing or partner services, continues to be an important public health strategy in the control of infectious diseases, including such well-known infections as sexually transmitted diseases (STDs) and HIV and including such emerging infections as severe acute respiratory syndrome (SARS) and monkey pox. Health officials in the United States have been using the public health practice of notifying and treating sex partners as an important intervention to control the spread of syphilis, gonorrhea, and chlamydia (Centers for Disease Control and Prevention, 2001a). To reduce the rates of transmission of and re-infection with these bacterial STDs, it is important not only to treat the patient (also referred to as the index case) who is seeking care with effective antibiotics but also to provide medical evaluation and treatment to the sex partners (Centers for Disease Control and Prevention, 2002; Rothenberg & Potterat, 1999). Partner notification and management is also becoming an increasingly important strategy in the control of HIV infection, especially in the new era of highly effective therapy (Centers for Disease Control and Prevention, 2003a).

Concomitant with the public health practice of partner notification and management, investigators have conducted scientific studies to assess current practices of partner notification and management and to develop and evaluate new strategies (Martich, St.Lawrence, Hall, & Hartsfield, 2002). While public health practice is governed by public health law as stipulated in state laws and by the professional code of conduct for health care providers, investigators conducting scientific studies are governed by the federal regulations for the protection of human subjects (Gostin, 2000; Centers for Disease Control and Prevention, 2001b; Institute of Medicine, 2001). As required by the federal regulations (also known as the Common Rule), members of institutional review boards (IRBs) review and approve study protocols prior to execution of studies to ensure that rigorous procedures are in place to protect the rights and welfare of study participants (OPRRI Reports, 1991). While study procedures are presented in great detail in study protocols, they are described very briefly in published articles. The rigorous debates and discussions that develop between investigators and IRBs are rarely summarized in published articles. As a result, the community of investigators and IRB members do not have the benefit of a cumulative source of information that highlights the ethical concerns raised and the procedures implemented to protect the rights and welfare of study participants.

The purpose here is to highlight the ethical concerns related to the principle of beneficence as this principle applies to studies of partner notification and management. We consider concerns related to threats to privacy and confidentiality, breakdown in relationships, and medical safety of sex partners provided with medications for the treatment of bacterial STDs. We suggest procedures that have been used or can be used to minimize unintended negative consequences, and we discuss measures to enhance compatibility of scientific goals, public health practice, and ethical principles.

The Practice of Partner Notification and Management

The public health practice of partner notification and management involves the processes of informing sex partners of patients with STDs or HIV of their potential exposure to infection and offering them treatment and counseling for risk reduction and prevention (Centers for Disease Control and Prevention, 2001a). The first objective of partner notification and management is to notify sex partners at risk so that uninfected partners might avoid acquiring infection and so that infected partners might avoid transmitting infection. The second objective is to reduce re-infection rates and to reduce the burden of disease of high-risk sexual networks and in the community at large (Potterat, 1997; Potterat, 2003).

Partner notification and management is a multi-step process that begins with eliciting information about sexual contacts from the index cases; notifying those at risk for being infected; determining those who are infected and those who are not; and assisting the sex partners in receipt of diagnosis, treatment, and
Local public health departments are mandated to elicit, notify, and provide assistance in activities related to the medical evaluation, treatment, and risk-reduction counseling of sex partners. These partner management and notification services are based on similar principles for both STD and HIV. The services are always voluntary on the part of the infected persons and their partners; hence, to increase cooperation, the information obtained is treated as confidential. Public health officials endeavor to have the services science-based, to be delivered by knowledgeable, skilled, and trained staff in a non-judgmental and sensitive manner, and to be culturally appropriate (Centers for Disease Control and Prevention, 2001a).

The four main practices of patient referral, provider referral, conditional (also known as contract) referral, and partial assistance with notification, are used to contact sex partners exposed to HIV or to bacterial STDs (Centers for Disease Control and Prevention, 2001a; Mathews et al., 2001). In patient referral, the index cases are encouraged to notify their partners on their own and to inform them of the need for medical followup. In provider referral, either the health providers treating the index cases, disease intervention specialists, or other trained staff members of local health departments carry out the elicitation, notification, and management activities. In conditional referral, index patients are encouraged to notify the partners, and then providers or disease intervention specialists carry out the notification and management activities if the partners do not show up for or receive medical evaluation and treatment within a specified period of time. In partial assistance with partner notification and management, health staff members contact the partners that the patients themselves indicate they cannot or will not contact.

Scientific Studies of Partner Notification and Management

While partner notification and management services are offered to the majority of patients with syphilis, they are offered to almost one half of the patients with HIV in areas where reporting of HIV infection is mandatory, and they are offered to less than a quarter of patients with gonorrhea and chlamydia (Golden et al., 2003; St. Lawrence et al., 2002). Because of the low coverage of partner notification and management services and the shortage of resources for these services, and despite their importance as one component of a comprehensive prevention strategy to control highly prevalent STDs, investigators are developing and evaluating new strategies. For bacterial STDs, the new strategies include giving study participants prescriptions for medications or medications to deliver to sex partners (“partner-delivered therapy”) or involving pharmacies in the delivery of the medications.

The public health practice and the scientific studies of partner notification and management raise ethical concerns, in part because these practices often involve exchange of private, identifiable information regarding sensitive topics – sex and STDs (Rivas & Sulmasy, 2002). Thus, care is taken to prevent or minimize potential harm, including threats to privacy and breaches in confidentiality; and the potential for abuse, violence, and breakdown in relationships. A major additional concern relates to the medical safety of sex partners provided with prescriptions or medications for the treatment of bacterial STDs in the absence of laboratory testing, taking of medical history, and clinical examination.

The Ethical Principle of Beneficence and Regulatory Requirements for Scientific Studies

The Belmont report highlighted the importance of three principles in the ethical conduct of scientific studies – the principles of respect, beneficence, and justice (The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 1978). The principle of beneficence requires investigators to ensure that the benefits of research are proportionate to the risks assumed by study participants and to design study protocols that will provide valid and generalizable knowledge. This principle is enforced by federal regulations requiring that risks to participants
to be reasonable in relation to the anticipated benefits and in relation to the importance of the knowledge that may be gained (OPPR Reports, 1991). The federal regulations also require that risks to study participants be minimized through the use of procedures that are consistent with sound scientific design and that do not unnecessarily expose participants to risk.

The IRBs are committees of researchers, providers, patients, and community representatives. They are mandated to review, approve, and monitor federally funded research to ensure that scientific studies meet federal regulations (OPPR Reports, 1991). IRBs' approval of scientific studies indicates that the studies contain adequate protections for the rights and welfare of study participants. IRBs usually ask whether the study will pose a risk of harm to study participants, assess whether the study design and procedures proposed by the investigators minimize potential risks, and judge whether the potential benefits of the study outweigh the risks (Amdur & Bankert, 2002). More specifically, IRBs evaluate the procedures that will be used for data collection and for data management, including the procedures that will be used for storing and transmitting data, for creating or eliminating linkages between data and identifiers, and for re-contacting study participants for follow-up data collection or for reimbursement. Accordingly, IRBs check whether the procedures proposed by investigators sufficiently protect the privacy of study participants and ensure against a breach in confidentiality. The IRBs also review the harms that may result and the safeguards that are in place to minimize these harms. IRBs usually define harm as bad outcomes or as adverse events—physical, social, or emotional—that may affect study participants as a result of being in a study.

Our search strategy included studies of patients infected with STDs or HIV, regardless of study design or population. Studies with different study designs or with different populations (e.g., patients or providers) have to meet different regulatory and review requirements because of the varying levels of risk expected to be encountered by study participants. Studies that use experimental designs (e.g., randomized clinical trials) to evaluate new strategies in comparison to standard of care receive more stringent scrutiny from IRBs as compared to case–control studies and may generate more heated debates about ethics. Surveys with health care providers give information about practices of partner notification and management. Authors of all studies that collected data from patients (as study participants) reported that their studies were approved by IRBs.

**Summary of Study Results**

Four of the ten studies were published in 2003, another four in 2002, and the remaining two in 2001 (Table 1). Two studies (Golden et al., 2003; St. Lawrence et al., 2002) surveyed a national sample of health care providers about practices of partner notification and management. The remaining eight studies were conducted with patients, and they assessed their preferences and behaviors regarding partner notification and management. Three studies examined effects of partner notification and management on relationships (Fortenberry et al., 2002; Hoxworth et al., 2003; Kissinger et al., 2003), two studies examined effects of patient-delivered therapy (Golden et al., 2001; Schillinger et al., 2003), and one study assessed cost effectiveness of partner notification and management (Reynolds et al., 2001).

Five of the ten studies used cross-sectional designs (Carballo-Dieguez et al., 2002; Golden et al., 2003; Hennessy et al., 2002; St. Lawrence et al., 2002; Reynolds et al., 2001). Three studies used a cohort design (Fortenberry et al., 2002; Hoxworth et al., 2003; Kissinger et al., 2003). Two studies were randomized clinical trials (Golden et al., 2001; Schillinger et al., 2003). Except for one study that used secondary data (Reynolds et al., 2001), authors of all other studies collected primary data from study participants.

**Methods**

**Procedures**

We conducted computerized and manual searches to locate the ten most recent published articles on studies of partner notification and management published as of May 2003. We used three strategies to locate these studies. We searched the Medline database, networked with researchers, and conducted manual searches of journals and reference lists.
Different procedures were reported in the studies to protect the privacy, confidentiality, relationships, and medical safety of partners (Table 1). These procedures included obtaining informed consent from participants, training study staff and participants, and using appropriate procedures to deliver the information to the partners. Because sex partners were not enrolled as or reported to be “study subjects,” investigators of all the studies reviewed did not report that informed consent was obtained from the partners.

<table>
<thead>
<tr>
<th>First Author and Publication Year</th>
<th>Procedures</th>
</tr>
</thead>
<tbody>
<tr>
<td>Golden et al., 2003</td>
<td>Privacy: NA; Confidentiality: NA; Relationships: NA; Medical Safety: NA</td>
</tr>
<tr>
<td>Hoxworth et al., 2003</td>
<td>Privacy: Potential participants were first contacted by a health worker who forwarded names of eligible and interested individuals to study staff members. Trained study staff members were experienced in discussing sensitive information with study participants. Interviews were conducted at a location selected by participant (home, office, park, health department, or clinic). Confidentiality: Those who had mental health problems, were intoxicated, or had impaired cognitive function were excluded from study participation. Participants signed informed consent. Participants provided information about their partners by using first names, nicknames, code names, or initials. Study staff members used name identifiers, age, birth date, last sexual encounter, and partnership duration to match the data provided by participants with the data recorded by state health workers. Relationships: When state health workers notified partners about their potential exposure to STDs, they did not give them the names of those who reported them as their sex partners. Similarly, health workers did not give the participants the names of the partners who were notified about potential exposure to STDs. Medical Safety: NA</td>
</tr>
<tr>
<td>Kissinger et al., 2003</td>
<td>Privacy: Disease intervention specialists described the study to index patients first and then gave the names of those who agreed to participate to study staff members. Confidentiality: Those who refused to give the names of their sex partners from the previous three months were excluded from study participation. Informed consent was obtained from participants. Participants were asked to name their recent sex partners and to provide locating information. Participants were told that study information was kept confidential and was protected by physical security and by state laws and was not shared with state health workers. Relationships: Participants were given a choice about how to notify their partners. If they chose not to notify their own partner(s) or chose to notify their partner(s) but the partner(s) did not come in for testing, within the notification period, disease intervention specialists notified the partners. Medical Safety: NA</td>
</tr>
<tr>
<td>Schillinger et al., 2003</td>
<td>Privacy: NR Confidentiality: Partners of previous 60 days were identified by first names or by initials. Relationships: Participants were asked whether they could contact partners and notify them about STD infection, whether they expected partners to follow treatment, and whether they had concerns that telling partner about the STD infection could result in violence or change in relationship.</td>
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*Table 1 cont. next page*
### Medical Safety

Pregnant women, those with an adverse reaction to antibiotics, and those co-infected with other STDs were excluded from study participation. Each participant was given as many as four doses of azithromycin to deliver to partners (one dose per partner named) and was instructed to tell each partner about exposure to STDs and need for treatment. Each medication dose was labeled with medication name and with name and phone number for a health care provider, with warnings about contraindications and possible adverse effects of medication, and with advice to abstain from intercourse until 7 days after treatment. Participants provided their partners with a study fact sheet on Chlamydial infection.

### Privacy

Clinic staff used a study script to describe study to clients.

### Confidentiality

Participants responded to questionnaire anonymously and then deposited them in a locked box. No identifying information was collected on partners.

### Relationships

NA; Medical Safety: NA

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### Carballo-Dieguez et al., 2002

- **Privacy**: Clinic staff used a study script to describe study to clients.
- **Confidentiality**: Participants responded to questionnaire anonymously and then deposited them in a locked box. No identifying information was collected on partners.
- **Relationships**: NA; Medical Safety: NA

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### Fortenberry et al., 2002

- **Privacy**: Trained study staff.
- **Confidentiality**: Written informed consent from participants and a waiver of parental permission.
- **Relationships**: Patients provided data on each of the 4 most recent partners during previous 2 months by using initials or first names.
- **Medical Safety**: NA

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### Hennessy et al., 2002

- **Privacy**: Participants provided data anonymously.
- **Confidentiality**: Consent form was read to each potential participant. Completion of survey was used to signify consent. Participants dropped their completed questionnaires in a box.
- **Relationships**: NA; Medical Safety: NA

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### St. Lawrence et al., 2002

- **Privacy**: NA; Confidentiality: NA; Relationships: NA; Medical Safety: NA

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### Golden et al., 2001

- **Privacy**: Study investigators solicited permission of clinicians before staff of health departments contacted index cases about study participation.
- **Confidentiality**: Those who were intoxicated or had psychosis precluding informed consent were excluded from participation. Homeless people were also excluded from participation if homelessness precluded followup. Participants provided oral informed consent. Study personnel offered participants and partners who did not want to receive medication through a pharmacy a partner packet that can be obtained at an STD clinic, or delivered to their homes or work, by mail or by study staff.
- **Relationships**: Participants were interviewed about each sex partner in the 60 days preceding diagnosis. Study staff members offered to contact partners of participants who said that they were unable or unwilling to contact. Study staff members mailed or delivered the partner packets to the partners of those who preferred not to pick up the medication from a pharmacy.
- **Medical Safety**: Partner packets of participants with gonorrhea contained single doses of cefixime 400 mg and azithromycin 1.0 gm. Partner packets of participants with Chlamydia contained azithromycin 1.0 gm. Packets provided to partners also contained condoms, instructions on taking the medication(s), a pamphlet about STD prevention, and instructions advising partners to seek medical care and informing them that such care is available at STD clinics at no cost.

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### Reynolds et al., 2001

- **Privacy**: NA; Confidentiality: NA; Relationships: NA; Medical Safety: NA

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NA: Not Applicable; NR: Not Reported
Ethical Considerations
Privacy and Confidentiality

Although the concepts of privacy and confidentiality are related, they address different concerns. Privacy refers to the ways in which investigators gain access to personal information about and from study subjects, and confidentiality refers to the ways in which investigators handle and use this information (The National Bioethics Advisory Commission, 2001). Thus, privacy refers to how individuals share information about themselves with others, and confidentiality refers to how shared information is handled. While privacy is influenced by relational, cultural, and social characteristics, confidentiality is influenced by security measures.

Although study participants and the public are generally supportive of research, they often want to be assured that their personal data are protected and that threats to privacy or breaches in confidentiality are prevented. Two federal regulations attest to the importance of protecting study participants from unauthorized or inadvertent use or disclosure of personal data (OPRR Reports, 1991; Centers for Disease Control and Prevention, 2003b). The new Privacy Rule (otherwise known as the Health Insurance and Portability and Accountability Act or as HIPAA), requires the use of authorization forms for use of personal data collected by certain health care providers. The Common Rule requires the use of informed consent.

Procedures that may be adopted to minimize concerns about privacy and confidentiality include training clinical and research staff, using appropriate procedures to handle study data, implementing an enabling informed consent and authorization process, and choosing appropriate wording to inform the partners.

The need to train clinical and research staff members

Training courses in ethical principles and federal regulations and in procedures that are study-specific, along with high-quality monitoring of study staff members are important measures that can be used to reduce risks to privacy and confidentiality. Institutional policies and federal requirements now uniformly require that all study staff members engaged in federally funded research take ethics courses covering the importance of and the standards for ensuring the rights and welfare of study participants. Many institutions provide “scientific ethics verification certificates” and an “ethics number” to those who pass the test given after participation in the courses. All study staff members, including clinicians (e.g., physicians and nurses) and investigators, need to take these courses.

The importance of adopting appropriate procedures for handling study data

Strategies for handling study data include coding the data to protect the identity of the partners. This can be done by using identification numbers, pseudonyms, or initials, storing the data in locked filing cabinets, using passwords to protect computerized databases, asking trained staff members to sign confidentiality agreements, limiting staff access and time to identifiable data, destroying identifiable data after the study is completed, and ensuring that individual partners cannot be identified when the results are published. As an example, investigators of studies that provide medications to sex partners may use for the study tracking forms identification numbers, rather than names, to indicate the specific medications given to each partner. Investigators, then, need to keep these forms separately in a locked cabinet or in a password-protected computerized file, away from the form that links the names of the partners to the identification numbers.

The critical importance of implementing an enabling process and using clear documents for informed consent and authorization

In scientific studies, investigators are encouraged to adopt a truly informed consent and authorization process and to use clear and complete documents as one way for informing study participants of the risks for privacy and confidentiality and of the procedures taken to minimize these risks. While the need for obtaining informed consent and authorization or for requesting IRBs to grant a waiver for this process stems from the ethical principle of respect, the ethical principle of beneficence refers to the need to explain clearly to study participants the risks and benefits associated with sharing their personal data. Therefore, the process and documents of informed consent and authorization.
should inform the study participants about the use of their personal data and should describe adequately the reasonably foreseeable risks associated with privacy and confidentiality. These processes and documents should explain to participants how their data would be obtained, used, handled, shared, stored, or disclosed. This process is not simply or only a risk-management or a risk-reduction strategy but rather an important step for the realization of fundamental ethical principles (Brody, 2001).

By virtue of their clinical jobs, health care providers and disease intervention specialists need to adhere to the privacy and confidentiality laws pertaining to state-level disease notification laws, and they have an obligation to not reveal the name or identity of the index patients to the partners (Gostin, 2000; Centers for Disease Control and Prevention, 2001a). Therefore, it may be argued that when health care providers participate in scientific studies, such studies do not introduce additional physical, social, or emotional risks for the partners in comparison to public health practice, and any additional risk that a person has as a result of being part of a study, could be considered minimal. Although these arguments may be valid, it is still the obligation of investigators to explain clearly in the process and documents of informed consent and authorization the risks associated with privacy and confidentiality. Study participants and partners (if partners have also consented) need to make a voluntary decision about participating in the study.

The need to use appropriate wording to inform the partners

Investigators may choose to adopt appropriate wording to protect the privacy and confidentiality of partners. When there are concerns that other people may open envelopes sent by study investigators and read the information about the partners’ health status, it seems judicious that investigators use appropriate safeguards. For example, investigators may choose to use unlabeled envelopes that do not have pre-printed identification labels indicating the name of the facility conducting the study, and investigators may use unlabeled stationery so that identifying information cannot be read from the outside of the envelopes. Investigators may also limit the information provided in notification letters sent to partners and may choose to adopt or adapt the standard information provided in the letters sent by the health departments. Instead of stating in the letter that the sex partner has been exposed to a specific STD and may have been infected, study investigators may choose to state that the partner needs to follow up with the named health facility about an urgent health matter. Investigators may also choose to use medication labels that do not state that the partners have a certain STD. Because several medications prescribed for bacterial STDs (e.g., cefixime and azithromycin) are routinely prescribed for other illnesses, the use of a standard medication label may protect the rights and welfare of partners.

Effects on Relationships

Opponents of partner notification and management strategies have asserted that these strategies result in partnership dissolution and in abuse or violence, and that they increase the acquisition of new infections through the formation of new partnerships (Potterat, 2003). On the contrary, public health advisors and disease intervention specialists (who engage in public health practice) have argued that there is no indication of adverse events. Recent studies have showed that partner notification and management, compared to other strategies or to the norm of everyday life that does not include partner notification and management, does not result in increased damage to relationships (e.g., increase dissolution of partnerships or formation of new partnerships) or promote violence and that, if anything, exposure to partner notification and management contributes to safer behaviors (e.g., increased condom use) (Kissinger, Niccolai, Mangus, & et al., 2003; Hoxworth et al., 2003). However, these studies have also reported high rates of partnership dissolution (about half to nearly two thirds) and new partnership formation (about 16%) for participants in all study groups.

When partner notification and management strategies are being evaluated as part of a study, IRBs and investigators are subject to additional levels of scrutiny, even when the proportion of negative unintended consequences is small or not different in comparison to public health practice or to risks of daily life. Each incident of a negative consequence is important, and each
incident may assume larger prominence if encountered in a scientific study. Therefore, efforts to prevent or minimize negative consequences are extremely important. In both public health practice and in scientific studies, participants tend not to notify partners they fear or partners who have abused them in the past. However, it is still important to reach these partners because they may reinfect the index cases and others in the community (Rothenberg, Paskey, Reuland, Zimmerman, & North, 1995; Rothenberg & Paskey, 1995; Koenig & Moore, 2000). In addition, participants may not be able to predict which partner might become abusive once the participant discloses information about an infection with a certain STD or with HIV. In many cases, even when partners are not told of the names of the index patients during the process of partner notification and management, they may guess – correctly or incorrectly – who the index case was. Some notified partners may have only one sex partner who could be the index case; others may learn the identity of the index case through discussion with all partners. Wrongful attributions, or even correct attributions, may cause harm to the study participants. Thus, there is a need for investigators to adopt procedures to minimize the risk of harm to relationships, including informing and training study participants and engaging them in the discussion on the appropriate modes to deliver the partners’ packets.

The need to inform and train study participants

Staff members need to inform participants about the risks for abuse, violence, or breakdown in relationships and to include this information in the consent forms, also stating that participants should not approach any partner they think may get abusive. Investigators may also choose to provide participants with a list of sites where they can receive counseling and shelter and to make provisions for professional help. In addition, investigators need to train study participants in how to notify and inform partners, similar to how staff of local health departments train the index patients when these patients choose patient referral (Centers for Disease Control and Prevention, 2001a).

Medical Safety of Sex Partners

Although staff members of most local health departments and private sector physicians do not provide patients with medications to give to their partners for the treatment of bacterial STDs, some report that they have done so (St. Lawrence et al., 2002; Golden et al., 1999; Golden et al., 2001; Golden et al., 2003). While procedures in clinical or public health practice and state laws could be used to justify what investigators can do in scientific studies, IRBs may still raise concerns about the medical safety of partners when the partners are not asked about drug allergies, examined or treated by health care providers, or informed about antibiotic resistance (Savulescu, 1998).

Some investigators may argue that partners receiving medications for bacterial STDs as part of a study may not be at a different level of risk from partners receiving such medications as part of standard care. They cite different medical reasons. Commonly used oral medications (e.g., cefixime, penicillin, and azithromycin) are prescribed for treating bacterial STDs, which are also, when used as part of standard public health practice for partner notification and management, taken by partners at home without medical evaluation or supervision. Serious adverse reactions or serious allergic reactions to any of the bacterial STD medications are rare and are unlikely because most of the medications are given in a single dose.

Finally, although participants could sell the medications they are supposed to deliver to their partners, this risk is low because participants are given the minimum doses, and the medications are relatively inexpensive. Still, investigators may need to adopt procedures to minimize the potential for negative side effects of patient-
delivered therapy, including informing the partners about the medications and having staff members available to respond to emergency questions or situations.

The importance of informing partners about the medications and the availability of medical staff members

Staff members can instruct study participants, partners, and pharmacists participating in patient-delivered therapy about the proper use of the medications; the lowest efficacious dosage needed for treatment and for avoiding development of antibiotic resistance; the recommended intake mode; the potential side effects; and precautions for avoiding the medications if allergic, pregnant, or after consuming alcohol. The labels on the medication bottles can also include the standard warnings provided by pharmacists and should include an emergency 24-hour contact phone number for the medical staff members of the scientific studies.

Discussion

The ethical principle of beneficence, the standards for scientific studies, and the code of federal regulations for the protection of human participants are three important underpinnings in the development, evaluation, and implementation of scientific studies of partner notification and management. We discuss options that might be used to enhance compatibility of scientific goals, public health practice, and ethical principles.

The Need for a Forum to Exchange Information on Ethical Considerations

Over the past decade, an extraordinary number of articles and reports have documented the inefficiencies in the process of IRB approvals (The National Bioethics Advisory Commission, 2001; Institute of Medicine, 2001; Federman, Hanna, & Rodriguez, 2002). While IRB members get frustrated when study protocols do not provide adequate information required by ethical principles and federal regulations, investigators question the importance of this information in protecting the rights and welfare of study participants and their partners. Often both groups get bogged down by concerns that get labeled as minutaie by study investigators and as critical by IRBs. Consequently, the richness of the debate about important ethical considerations for critical public health topics takes a back seat, and, most importantly, is not given a platform for scientific communication and exchange. The information exchange between investigators and IRBs remains in their files and drawers, although jokes about the process are often shared orally and sarcastically. Thus, important issues are often not summarized and brought to the attention of the scientific community, unless an extraordinary situation brings it to the forefront, as in the case of the vigorous debates, scientific conferences, and extensive publications on the ethical ramifications of placebo-controlled trials for maternal-child transmission of HIV infection (Annas & Grodin, 1998; Lurie & Wolfe, 1997). The lack of a regular forum for summarizing the ethical principles and procedures for a given scientific topic hinders the progress of ethical inquiry and may indeed affect the rights and welfare of study participants. While there is no need to let the media and adverse events drive the discussion of ethical considerations in public health practice and research, it seems important that investigators agree on a format for summarizing the important ethical discussions debated between investigators and IRBs.

We suggest that published articles include a subheading labeled “ethical considerations,” under the methods section, similar to the subheading labeled “statistical methods.” Investigators over the past thirty years have gradually accepted the importance of reporting statistical methods and procedures (e.g., power calculations and statistical tests) for the interpretation of scientific results and have accepted the importance of reporting relevant data for advancing the field of meta-analysis (Cooper & Hedges, 1994; Johnson et al., 2002). These statistical summaries are useful for understanding how the data were analyzed and for interpreting the results. Similarly, investigators may summarize the procedures implemented in their studies to protect the rights and welfare of study participants. Such summaries, if reported in the published articles we reviewed, would have been helpful to our study. Investigators may come to accept gradually the importance of summaries on ethics-related considerations for enhancing the compatibility of scientific goals and ethical principles. These summaries may lead to advances
in the ethics of public health research and practice, especially if care is taken to enhance the benefits of such summaries and to minimize concerns of editors (e.g., lack of space in printed journals) and of investigators (e.g., negative use by the popular media).

**Research on Practice or Standard of Care**

In applying the ethical principle of beneficence to the review of scientific protocols, IRBs are required to examine the risks that could be encountered by study participants; to ensure that such risks are justified by the potential benefits that study participants or society may receive; and to request that investigators implement procedures to minimize these risks. In order to conduct the risk-benefit analyses, IRBs need to assess whether they need to carry out these analyses in absolute terms (e.g., risk expected to participants enrolled in a given study arm in experimental studies) or in comparison to standard of care. In addition, in order to classify studies as “minimal risk” or as “more than minimal risk,” IRBs are required to assess both in absolute and in comparative terms the potential risks expected in scientific studies versus standard of care. Such judgments are difficult and may often lead different IRBs to different conclusions about what seems to be the same study protocol or the same public health topic. Therefore, it is important for investigators to provide IRBs with information on the scope and magnitude of the ethical concerns encountered in standard of care and with information on the ways in which the concerns are expected to differ in scientific studies. Collection of data and development of databases on harm in public health practice and in scientific studies may help quantify the type, magnitude, and severity of harm and may facilitate the development of appropriate procedures for prevention and damage control. It seems equally important that investigators and IRBs also consider the level of unavoidable risk that is acceptable in public health practice and in scientific studies of partner notification and management.

**Generalizability of Study Results**

Generalizability of results is an important scientific criterion, also embraced by the ethical principle of beneficence. When conducting a risk-benefit analysis for a certain study, it does not seem ethical to subject people to risk if the results of the study are not going to be valid and generalizable (OPRR Reports, 1991). When fears of threats to privacy and confidentiality, of domestic violence, of medical safety or of other negative consequences prevent participation in scientific studies, there could be important consequences for the generalizability of study results and for the transfer of results to practice. Efforts to translate research results for program use are gaining increased attention in the prevention efforts of HIV and other STDs (Sogolow et al., 2000).

Biased participation or exclusions from the study sample may take place before the study has started, after it has started, or while it is in progress. For example, generalizability of results in cross-sectional or cohort studies may be called into question when investigators, on the basis of assessments done at the time of screening or on the basis of participants’ preferences revealed during or after enrollment, exclude participants who are unable to deliver the packets to their partners because of the potential for unintended negative consequences. In experimental studies, randomization integrity could be compromised if investigators switch participants at risk for unintended negative consequences to a study arm that carries a lower risk for such consequences. The risk for unintended negative consequences may also be associated with high or differential attrition rates. Attrition rates influence generalizability of results and the ability to interpret the results. Other related scientific concerns associated with exclusion of certain participants include the time needed to enroll “eligible” participants, the availability of statistical power to carry out the analysis, and the ability to carry out intention-to-treat analyses.

Exclusions and biased participation have important implications for public health practice, especially when excluded people are at risk for reinfections. Investigators would need to assess carefully the overall effectiveness of biased participation in scientific studies, especially when study samples do not mirror the full spectrum of patients who are likely to receive partner notification and management as part of standard care.

While investigators may argue that participation bias and generalizability concerns due to ethical issues are hypothetical and IRBs may argue that such concerns are real, it seems impor-
tant that data, rather than hypothetical scenarios, guide the debates between the investigators and IRBs. Collection of data on ethics-related factors that influence implementation of scientific studies and interpretation of results would facilitate the resolution of such debates and would help investigators and ethicists to generate procedures to optimize both scientific and ethical integrity.

**Partner Notification and Management of Other Infectious Diseases**

The ethical and IRB concerns that could be raised in studies of partner notification and management for bacterial STDs or HIV exemplify many of the concerns that could be raised in studies of other infectious diseases, such as tuberculosis (Klovdahl et al., 2001; Klovdahl, 2001), in studies of family genetics (Botkin, 2001), and in network-related studies (Friedman & Aral, 2002). Hence, a deep understanding of the ethical principle of beneficence and of the requirements of the federal code of regulations for the protection of participants and their partners is important for the prevention efforts that focus on dyads, networks, families, and even communities.

**Conclusion**

The beneficence principle is an important ethical principle that affects the conduct of scientific studies (OPRR Reports, 1991; The National Bioethics Advisory Commission, 2001). This article discusses the complex concerns related to the ethical principle of beneficence that face investigators and IRBs as they review scientific studies of partner notification and management for bacterial STDs or HIV. Other issues that deserve discussion include concerns related to the ethical principles of respect and justice, and concerns that are specific to other resource-rich and resource-limited countries.

Commitment to the responsibility of conducting scientifically sound ethical research and to the preservation and protection of public health are important principles in guarding the rights and welfare of study participants and their partners. No matter what regulations and standardized forms that oversight committees, government, or institutions have in place, it is still the responsibility of investigators to treat their study participants and partners with respect and to protect their rights and welfare. As the relationship between patients or study participants and their partners is important for the prevention and control of STDs or HIV, a collegial relationship, free of conflict of interest, between investigators and IRBs is also important for enhancing the scientific and ethical integrity of studies of partner notification and management.
Reference List


Planning in an Academic Matrix Research Center

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Abstract

An effort was launched in 2001 to develop a strategic plan for the Rebecca and John Moores UCSD Cancer Center, an organized research unit and NCI designated comprehensive cancer center of the University of California, San Diego. The large planning project was intended to add structure to the decision-making surrounding the further development of the Cancer Center and the imminent ground breaking for a new multi purpose building. The project entailed a critical analysis of the characteristics of the center, input from its senior leaders and a set of benchmarks against which to measure its progress and productivity. The project took approximately one year to produce a five-year plan in concert with the NCI core grant project period. The Plan analyzes the Center from a programmatic and business perspective, identifying strengths and weaknesses and prioritizes the investment of its developmental funds.

Introduction

To reach a goal, concepts must be shaped into designs then set into a plan that leads to implementation. Strategic planning is a disciplined effort to produce fundamental decisions and actions that shape and guide what an organization is, what it does, and why it does it, with a focus on the future. (Adapted from Bryson’s Strategic Planning in Public and Nonprofit Organizations). So it is in the Rebecca and John Moores UCSD Cancer Center, an NCI designated comprehensive cancer center at the University of California, San Diego. This report will discuss our approach to planning, the essential elements, the manner in which we foresee the plan being actualized, and the metrics applied to measure progress. Planning in the Cancer Center is a complex, fluid effort due primarily to its matrix academic environment, but also because its goals intersect research and patient care components of the institution.

Although many use these terms interchangeably, strategic planning and long-range planning differ in their emphasis on the assumed environment. Long-range planning is generally considered to mean the development of a plan for accomplishing a goal or set of goals over a period of several years, with the assumption that current knowledge about future conditions is sufficiently reliable to ensure the plan’s reliability over the duration of its implementation.

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On the other hand, strategic planning assumes that an organization must be responsive to a dynamic, changing environment (not the more stable environment assumed for long-range planning). A common assumption has emerged in the nonprofit sector that the environment is indeed changeable, often in unpredictable ways. Strategic planning, then, stresses the importance of making decisions that will ensure the organization’s ability to successfully respond to changes in the environment. Rowley, Lujan, and Dolence state that it involves “arraying options through a process of opening up institutional thinking to a range of alternatives and decisions that identify the best fit between the institution, its resources, and the environment” (1997).

For the Moores UCSD Cancer Center, the needs for a strategic plan align with this principle, in that it has a certain level of stability in being funded in 2001 for five years by the National Cancer Institute. The Cancer Center has gained the status of NCI-designated comprehensive cancer center, and it also has begun construction of a 270,000 gross square feet multi-use building, presenting it with new programmatic and financial challenges. We approached the task of developing a plan by applying established principles of consensus and specificity.

### Developing the Plan

The effort began in August 2001 with the consensus of the Cancer Center’s senior leaders that a formal plan was of benefit and with their commitment to support the effort through their time and input. While the lead author of the plan was the Cancer Center’s administrator, it was conceived and reinforced by the director and involved the thoughts of dozens of individuals. Ringle and Updegrove suggest that in order for a technology effort to be successful, key individuals within the community—faculty, senior officers, and others—must understand the importance of an initiative and, to some extent, take ownership of it. This type of understanding and endorsement is best achieved when those individuals play a role in the formulation of the initiative itself, as they might during the planning process (Ringle & Updegrove, 1998). Pfeiffer, Goodstein, and Nolan (1985) note that a consensus-based mission statement can serve an additional, practical purpose in management planning; it can act as a guiding force, or priority standard, for allocating limited resources. We also wished to recognize the cyclical nature of the effort; continuously monitoring, benchmarked annually and intensively recast every five years. We drafted a time line (Figure 1).

#### Figure 1
**Time line**

<table>
<thead>
<tr>
<th>Event</th>
<th>Dates</th>
</tr>
</thead>
<tbody>
<tr>
<td>Outline</td>
<td>June 2001</td>
</tr>
<tr>
<td>First Draft</td>
<td>October 2001</td>
</tr>
<tr>
<td>Internal Review</td>
<td>December 2001</td>
</tr>
<tr>
<td>Annual Benchmarking timed to the</td>
<td>April 2002</td>
</tr>
<tr>
<td>grant progress report submission</td>
<td></td>
</tr>
<tr>
<td>Executive Level Review</td>
<td>February 2002</td>
</tr>
<tr>
<td>External Advisory Council Review</td>
<td>June 2002</td>
</tr>
<tr>
<td>Approved 5 year Plan</td>
<td>July 2002</td>
</tr>
<tr>
<td>Annual Benchmarking</td>
<td>April 2003</td>
</tr>
<tr>
<td>Annual Benchmarking</td>
<td>April 2004</td>
</tr>
<tr>
<td>Preliminary discussion of revisions</td>
<td>October 2004</td>
</tr>
<tr>
<td>Revised 5 year Plan</td>
<td>July 2005</td>
</tr>
</tbody>
</table>
Drafting the Plan was launched by interviewing the senior leaders, soliciting their ideas about what the Cancer Center represents and where it is heading. From those initial interviews the skeleton of the plan was laid out in various elements: the Cancer Center’s mission, goals, objectives, strengths and weaknesses, necessary actions and a set of benchmarks through which to measure and monitor its growth. The traditional format of a SWOT (Strengths, Weaknesses, Opportunities, Threats) analysis was applied, which evolved into a plan for the future.

The mission of the Cancer Center is the following:

The Moores UCSD Cancer Center is committed to promoting and sustaining excellence in basic, translational and clinical research, cancer prevention, and the highest quality of clinical care. Toward this goal, the Cancer Center exists to promote interdisciplinary research and the rapid translation of discoveries from the laboratory to the cancer patient; and, to seek to control cancer through interventions to treat the patient and prevent the disease in populations determined by genetic and/or environmental factors to be at risk of occurrence.

This statement encapsulates the Cancer Center’s identity and purpose and the mission are simple and straightforward without specific details about the patient care and research being conducted.

We next attempted to integrate the mission with the Cancer Center’s goals. We wanted to limit the number of goals, lest they be unwieldy, so we combined the goals (longer term) with the objectives (shorter term) to arrive at the following aspirations:

In order to continue to build the Cancer Center, maintain it as a Center of Excellence and offer the highest quality service to our research and community constituents, the broad objectives for the next five years are to (a) create the optimal environment for collaborative/translational science, (b) strengthen/restructure weaker programs, (c) develop large interdisciplinary research programs, (d) reprogram developmental funding emphasizing program project grants and Specialized Program of Research Excellence (SPORE) grants, (e) reinforce the clinical trials program, and (f) enhance internal and community services of the Center.

To efficiently address these objectives in a plan, we had to dissect the multifaceted components of the Cancer Center and organize them under the broad headings of: Research; Patient Care; Community Activities; the Role of the New Cancer Center Building. Under each heading we identified the current strengths and weaknesses, the objectives, the action plan and the metrics for evaluation. The selected strengths and weaknesses were a combination of comments from the NIH grant reviewers, our senior leaders, and the yardsticks we have applied internally to the performance of the programs.

The objectives, which were key to the plan, reflected the combined thinking of the Center’s leadership in the direction it was to take for the future. For example, the objectives for Research are stated: The Moores UCSD Cancer Center, in building a cancer research program of the highest stature, seeks to:

1. Assemble the most promising and productive scientific programs relevant to the strengths of the Cancer Center and the needs of the community/region.
2. Infuse the Cancer Center continually with new investigators of extraordinary potential and accomplishment from both within and outside of UCSD.
3. Foster further interaction among cancer scientists and physicians to achieve optimal programs, productive collaboration, and the highest quality patient care.
4. Utilize fully and effectively the new cancer center building commensurate with the mission to join basic, clinical, and behavioral scientists in their common objectives.

Perhaps most important to the plan are the actions necessary for actualization. They must be neither too limited nor too broad, but realistic to achieve the objectives. We stated our action items for research in the following manner.

1. Identify the most significant research strengths and weaknesses of the Cancer Center in order to determine how best to
build the Cancer Center.
2. Determine whether to focus on building on strengths or reinforcing weaknesses.
3. Build centers of excellence in major research areas.
4. Identify and implement the most effective channels for interaction.
5. Determine and prioritize the need for recruitments to the Center to complement existing areas of excellence, and develop weaker but promising areas.
6. Develop research and clinical programs for the new building that complement and integrate the other’s areas of expertise.
7. Retain the existing program structure for the current core grant performance period to test its merit. Certain programs will be scrutinized more closely to determine whether or how they should be continued.
8. Review the utilization of the shared resources and survey the membership for new Cancer Center services.
9. Continue the use of seed monies to promote new discovery and peer reviewed grant support.
10. Study the creation of tumor based programs to target translational research in those tumors which meet the NCI criteria for creation of new research programs.
11. Study the creation of new basic science programs to exploit the Center’s strengths in these areas.
12. Periodically review the membership of the programs to ensure reasonable productivity and proper fit. Participating members will be reviewed every three years and associate members will be reviewed bi-annually.
13. Create and implement more opportunities for collaboration and cross-fertilization of research.

Formulating objectives and implementing action plans comprised 50% of the plan, because without evaluation measures the plan would have no value. Thus, we needed to devise a means of measuring progress and productivity. We accomplished this by combining meaningful metrics with information readily available which minimized the risk of inaccurate or idiosyncratic data that could be tolerated in a strategic plan. Measurement of performance at least annually, but preferably more often, to evaluate the effect of specific actions on long-term results and on the organization’s vision and mission is important. (Pfeiffer, Goodstein, & Nolan, 1985)

We decided that the measurements would, for the most part, derive from data collected for the annual core grant progress report to the NCI because the progress report calls for considerable quantitative data and we could relatively easily identify them as metrics for the plan. For research they include the number of sponsored projects; the total direct costs; the total direct and indirect costs; the number of members in the Center; the number of publications which are intraprogrammatic and interprogrammatic; the number of seminars; the number of clinical trials; and the number of patients on trials. Pertinent metrics were developed for Clinical Oncology and Cancer Outreach, as well. Measures for the new building are deferred until its planned opening in 2004.

The plan concluded with action assignments to groups composed of members of the senior leadership to pursue the objectives. The assignments are now a formal part of senior leadership meetings in which progress reports are presented.

Developing a Business Plan

Accompanying the programmatic plan is the business plan, which seeks to place financial value and cost on the stated objectives. We determined to include in the business plan only the costs related to the growth of the Center, and not to its basic operations. We wanted to distinguish between the funds needed to operate versus those needed to reach the stated objectives. The budget represents three sources of funds: the NCI core grant, the University, and gifts and contributions. The major categories where funds will be applied are planning and evaluation, new research, shared resources, faculty recruitment, and outreach activities. Under each heading are specific cost categories; for example, under shared resources we have identified the major costs as new equipment, new shared resource development, technology opportunity support, and alterations/renovations. In addition to a categorical breakdown, we included a breakdown of costs by source.
Benchmarking Our Progress

We have now reported on two full years of progress using 2000-01 as a base. The statistics are on a positive slope in virtually all areas. Figures 2, 3, and 4 below illustrate the benchmarking of the strategic plan.

The creation, development and acceptance of the plan gives the Cancer Center a firmer foundation upon which to approach the future and measure our achievement. While the plan is not unalterable, major modifications will involve a process of consensus and approval. The project to create a strategic plan to project both the

Figure 2
Cancer Center Members

![Bar chart showing Cancer Center Members over years 1999 to 2002.]

Figure 3
Total Peer-Reviewed Publications

<table>
<thead>
<tr>
<th>Cancer Center Programs</th>
<th>1998</th>
<th>1999</th>
<th>2001</th>
<th>2002</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cancer Biology</td>
<td>113</td>
<td>137</td>
<td>243</td>
<td>252</td>
</tr>
<tr>
<td>Cancer Genetics</td>
<td>46</td>
<td>52</td>
<td>114</td>
<td>157</td>
</tr>
<tr>
<td>Cancer Pharmacology</td>
<td>19</td>
<td>28</td>
<td>33</td>
<td>11</td>
</tr>
<tr>
<td>Cancer Prevention &amp; Control</td>
<td>45</td>
<td>78</td>
<td>88</td>
<td>70</td>
</tr>
<tr>
<td>Cancer Symptom Control</td>
<td>37</td>
<td>63</td>
<td>54</td>
<td>75</td>
</tr>
<tr>
<td>Translational Oncology</td>
<td>68</td>
<td>61</td>
<td>150</td>
<td>124</td>
</tr>
<tr>
<td>Viral Malignancy</td>
<td>14</td>
<td>28</td>
<td>39</td>
<td>41</td>
</tr>
<tr>
<td><strong>Totals</strong></td>
<td><strong>342</strong></td>
<td><strong>447</strong></td>
<td><strong>721</strong></td>
<td><strong>730</strong></td>
</tr>
</tbody>
</table>

**Percent Change**

|                  | 31%  | 61%  | 1%   |

*Source for 1998 and 1999 data: CCSG 2P30CA-23100-17, 18
Source for 2001 data: CCSG 2P30CA-23100-19
Note: Data were not collected for Year 2000.*
Figure 4
Total Direct & Indirect Costs Support

Figure 5
Planning Cycle
actions and timing for further development of the Cancer Center proved to be a very valuable exercise. We now have a foundation upon which to build the Cancer Center and a schedule to follow. Figure 5 demonstrates the planning cycle we have gone through and expect to follow in the future, beginning with the NCI Support Grant Renewal in 2001 and continuing in the same vein beyond 2005.

References

