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FROM THE EDITOR'S DESK

From the Editor's Desk

Jeffrey N. Joyce, Ph.D.
Kansas City University of Medicine and Biosciences

The *Journal of Research Administration (Journal)* provides a scholarly forum for information and critical analysis of research administration topics to help our members meet their challenges in developing the research enterprise while assuring compliance with a myriad of agencies. In the April-May 2014 issue of The SRA Catalyst, Pamela Miller in "View from the Top" presented the summary of the peer interactions and discussions from the 2013 SRA Senior Leadership Institute (SLI) held at the Annual meeting in New Orleans, Louisiana. While the Institute was designed for and guided by individuals at the upper levels of administration within higher education and the non-profit and for-profit research communities; the issues are recognizable to all of us. There were a number of "super themes" that predominated in the community of research leaders:

- Research strategic plans for countries, states and institutions that align with short and long term economic development plans
- Re-examination of compliance and integrity issues
- Investment in research Infrastructure
- Ownership of IP in an open innovation environment that includes universities, industry, community and investors
- Issues with international collaboration and funding
- Diversification which leads to the need to seek out new funding agencies and understand new requirements of a variety of funding agencies

In this issue of the *Journal*, as with all issues, we endeavor to address these major themes, providing strategies for success, insight into regulatory compliance issues, research management, and research development. This issue includes four articles covering a broad range of topics. Nickson writing *"A Qualitative Case Study Exploring the Nature of New Managerialism in UK Higher Education and Its Impact on Individual Academics' Experience of Doing Research"* offers insight into the 'informal' strategies that researchers utilize to pursue their own research agendas within 'formal' management frameworks, suggesting that different management styles need to be developed to account for this. Williams writes in *"Research Synergy: The Graduate School of Public Health, the SDSU Research Foundation, and San Diego State University"* about his perspective in a case study of how the synergy between a graduate school and a separately incorporated non-profit research administration entity helped drive research growth for the entire university. Volpe and co-authors describe in *"The Resource Allocation Program at the University of California, San Francisco: Getting More from Intramural Funding Bucks"* their institution's commitment to a strategy for a shared administrative structure in allocating intramaural grant resources, that ultimately increased the extramural funding for several

programs. Finally, Jenkins presents in *"Trends in United States Biological Materials Oversight and Institutional Biosafety Committees"* his findings regarding the scope of biological materials regulatory oversight in the United States States, demonstrating the growth of biological materials oversight and dramatic rise in the number of Institutional Biosafety Committees. In it he discusses the important issue that many IBCs lack adequate staffing and oversight, and the implications at the national level.

I wish to remind all of the readers of the *Journal* that we want your contributions, and the Editorial Board is committed to helping each author or collaborating authors in the submission of a manuscript. It is your experience, point of view, or analysis of the literature that is important to our entire community.

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ARTICLES

Trends in United States Biological Materials Oversight and Institutional Biosafety Committees

Chris Jenkins, PhD, MPH, RBP, CHMM
Saint Louis University, School for Public Health and Social Justice
University of Missouri, Masters of Public Health Program
Western Institutional Review Board, Institutional Biosafety Committee Services (WIRB IBCS)

Abstract: *Biological materials oversight in life sciences research in the United States is a challenging endeavor for institutions and the scientific, regulatory compliance, and federal communities. In order to assess biological materials oversight at Institutional Biosafety Committees (IBCs) registered with the United States National Institutes of Health, Office of Biotechnology Activities (NIH-OBA), a survey was sent to institutions obtained through a Freedom of Information Act request in early 2013. This research article will highlight the findings from the survey and literature review of current industry requirements, and highlight best practices and trends from survey data for trends in research administration.*

The goals of this research were to understand the scope of biological materials regulatory oversight in the United States, review results from a cross-sectional survey of Institutional Biosafety Committees conducted in 2013, and discuss trends for research administration compliance and best practices.

Keywords: *biosafety, research compliance, research administration, Institutional Biosafety Committee, biological safety, NIH Guidelines, recombinant DNA, synthetic DNA, biological materials, human gene transfer, gene therapy, animal research, life sciences research*

Introduction

Since 1975 when the Asilomar Conference convened over recombinant DNA technology and led to the creation of the National Institutes of Health (NIH) Guidelines for Research Involving Recombinant DNA Molecules (recently changed to Guidelines for Research Involving Recombinant and Synthetic Nucleic Acid Molecules), advances in biotechnology and recombinant DNA (rDNA) have necessitated oversight and safety reviews of life sciences research with biological materials through Institutional Biosafety Committee (IBC) oversight in the United States (Berg, Baltimore et al. 1975, Jackson October 1972). Over time from the Guidelines initial implementation, it has become accepted by the scientific and biosafety communities that additional monitoring of non-rDNA biohazards by IBCs should occur (Talbot, King et al. 1981, Dutton and Hochheimer 1982, O'Reilly, Shipp et al. 2012).

In contrast to the detailed NIH requirements for oversight of federally funded research that involves human subjects, animals, and even recombinant DNA, no uniform standard exists for oversight over additional forms of biological materials used in research as there are for animals, radioactive materials, or human subjects. Since the current regulatory environment does not prescribe a one-size-fits-all solution for the regulation of all biohazards, each institution must craft its own mechanism knowing that there are layers of biohazard oversight beyond those prescribed in the regulatory environment (Harris, 2005). This flexibility presents institutions with a myriad of options and little guidance on how to oversee biohazards beyond those prescribed in the NIH Guidelines.

This research hypothesizes United States life sciences regulation for research involving biological materials fails to provide adequate biosafety and biosecurity oversight, and IBCs charged to oversee research with biological materials require additional regulatory guidance in order to protect people, product, and the environment. The expected outcomes will highlight regulatory limitations and statute gaps with biohazards in research, propose policy changes, and provide the regulated community current IBC practices and example methodologies for Institutional Biosafety Committees and institutions to adopt to enhance biosecurity and compliance with biological materials.

History of Recombinant DNA Technology and Oversight

Recombinant DNA (rDNA) technology is a relatively recent phenomenon. During a 1968 Senate Subcommittee hearing on a Joint Resolution to establish a new health science commission, Dr. Arthur Kornberg directed the subcommittee's attention toward the rapidly progressing field of molecular biology (Vettel, 1968). Dr. Kornberg noted important developments were near fruition and that the potential social impact of these advances could be far-reaching (Vettel, 2006). Dr. Kornberg was referring to discoveries which would provide the technical framework for the specialty commonly known as genetic engineering (Vettel, 1968). New techniques developing in this field would enable a researcher to recombine DNA, the hereditary material of the cell, in a very precise manner (Vettel, 1968). The rDNA introduced could provide a cell with the ability to manufacture products (for example, insulin) which were previously not part of the cell's make-up (Johnson, 2011).

In 1973, a group of scientists attended the Gordon Conference Session chaired by Drs. Maxine Singer and Dieter Sol to discuss the possibility of public health risks associated with genetic engineering (Singer and Soll, 1973). The concern was based upon the conjecture that the new techniques could accidently produce a recombinant molecule with hazardous characteristics (Hellman, 1973). It was speculated that an inadvertent modification of DNA in a previously harmless organism might enhance the organism's capability of producing a highly infectious disease (Singer and Soll, 1973). After extensive deliberation, the session's participants voted in favor of sending a letter to the National Academy of Sciences (NAS) suggesting that the academy consider the risks associated with genetic engineering and "recommend specific actions or guidelines" (Berg, Baltimore et al., 1974). In response to the Gordon Conference

letter, NAS appointed a panel of experts to study the risk question (Johnson). The risk question was to be addressed at a conference near Asilomar State Beach in California (Paul Berg, 1975).

Asilomar Conference

Prior to the Asilomar Conference in February, 1975, a call was issued by leading basic research scientists for a voluntary moratorium on life sciences research using rDNA technology in July, 1974 (Berg and Singer, 1995). For the moratorium, scientists agreed new rDNA technology created the potential for novel approaches in medicine, agriculture and industry, but also could result in unforeseen and damaging effects to human health and the environment. The moratorium would only be lifted after a conference was held to evaluate and regulate the risks associated with rDNA technology (Berg, Baltimore et al. 1974).

The conference, held at the Asilomar Conference Center in Monterey, California included scientists, lawyers, media, and U.S. government representatives. The primary goal of the meeting was whether to lift the moratorium, and if so, under which prescribed conditions rDNA research could be conducted in a safe and prudent manner. While little data beyond Berg's experiment existed at the time, despite opposition, the Conference ended with the understanding rDNA research should proceed but under strict guidelines (Berg, Baltimore et al., 1975). Such guidelines were collected and drafted into the 1976 Federal Register as the NIH Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines, 1976), and were revised multiple times immediately after and in the subsequent years, most recently in March 2013, with a slight modification of the title to become the NIH Guidelines for Research Involving Recombinant and Synthetic Nucleic Acids (National Institutes of Health, 2013). The rationale for prompt action by scientists and the government from 1973 to 1976 was to protect laboratory personnel, the general public, and the environment from unintended or intended harm rDNA research with replicating organisms could potentially cause (Berg and Singer, 1995). In order to facilitate local protection with rDNA, the concept of the Institutional Biosafety Committee (IBC) was formed as a requirement for local review of biological materials for institutions upon receipt of federal funding in the NIH Guidelines. This Committee was and is today a community represented group of scientific peers with oversight at each individual entity, on research with rDNA molecules at each institution (National Institutes of Health 2013).

Definition and Applications of Recombinant DNA Technology

An overview of rDNA and rDNA technology is provided followed by background on the evolution of the IBC. The NIH Guidelines define rDNA as "molecules that are constructed outside living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell, or molecules that result from the replication of those described above" (National Institutes of Health, 2013). Recently, changes to the NIH Guidelines now specify rDNA to also include synthetic nucleic acid research, due to advances in synthetic biology, and for the purposes of this document, research involving recombinant and synthetic nucleic acids will be referred to as rsNA (National Institutes of Health, 2013).

Recombinant and synthetic nucleic acids as a technology can be used because all organisms share the same chemical structure, with the only difference being the actual sequence of nucleotides (Lodish, 2000). Thus, when DNA from a foreign source is introduced into host sequences that can drive DNA replication and introduced into a host organism, the foreign DNA is replicated along with the host DNA (Brown, 2010). Consequently, the biological functions, and therefore applications and uses of rsNA are theoretically nearly limitless (Brown, 2010).

The most common application of rsNA is in basic life sciences research, where it is important to most current work in the biological and biomedical sciences (Brown, 2010). Recombinant DNA is used to identify, map and sequence genes, and to determine their function (Boyle, 2008). Recombinant DNA probes are employed in analyzing gene expression within individual cells, and throughout the tissues of whole organisms (Boyle, 2008). Recombinant proteins are widely used as reagents in laboratory experiments and to generate antibody probes for examining protein synthesis within cells and organisms (Alberts, 2008). While promising, rsNA is not without potential risk when manipulating the components of genetic heredity (Werkmeister and Ramshaw, 2012).

Risks of Recombinant DNA and Biological Materials

The history and use of recombinant DNA in biological organisms has a history of controversy, and no one understood the controversy more than Dr. Donald Frederickson. (Frederickson, 2000). Dr. Frederickson was the Director of the NIH in the mid-1970's and oversaw the rDNA technology controversy from start to finish with the issuance of the NIH Guidelines. While the possibilities and potential of rDNA seemed endless, researchers involved in rDNA experiments feared that they might produce unpredictable occupational and environmental hazards. For example, one risk was by increasing the virulence of viruses or the resistance of bacteria to treatment with antibiotics. The fear that gene splicing could produce epidemic pathogens was heightened by the fact that biologists were using microorganisms in their recombinant DNA research that have human hosts, most notably the bacterium E. coli.

The task to develop the principles formulated at Asilomar into a detailed set of technical guidelines on containment facilities and safety procedures in rDNA research fell to Dr. Frederickson (Frederickson). As the Director of the main funding agency for rDNA research, and the leading biomedical research facility in the country, NIH and Dr. Frederickson had both the institutional resources and the scientific authority to set laboratory standards in the United States, and by extension, for the rest of the research world.

Some scientists, including biochemist Erwin Chargaff, warned against regulation by NIH (Chargaff, 1977). In his eyes, it was an irreconcilable conflict of interest and an encroachment on the freedom of scientific inquiry for the agency that funded most rDNA research to also be the agency that regulated such research (Chargaff and Simring, 1976, Davis, Chargaff et al., 1977). Other scientists, including Nobel laureates James D. Watson, David Baltimore, and Stanley N. Cohen, called upon NIH in Science to devise guidelines for the containment of rDNA molecules so that researchers around the country could adhere to a common, predictable standard in conducting their experiments (Berg, Baltimore et al. 1974).

The controversy soon involved local citizens, public organizations, and politicians. In the summer of 1977, the city council of Cambridge, Massachusetts, held contentious hearings on rDNA research conducted at the city's universities, (Culliton 1976, 1977). It created the Cambridge Biohazards Committee to conduct site visits and review containment measures for all proposed experiments, in the name of protecting residents from potential health risks (1976, 1977). Similar measures were urged by Science for the People, an organization of community health activists in Ann Arbor, Michigan, home of the University of Michigan (SSG 1977). The environmental organization Friends of the Earth brought suit demanding that rDNA research proceed only after NIH issued a comprehensive Environmental Impact Statement, a time-consuming and complex task (Frederickson 1982). Other critics opposed rDNA research on ethical grounds, arguing that it amounted to an attempt to upset the order of nature by manipulating DNA, the code of life (Frederickson).

Congress was as divided over the issue of regulating rDNA research as well as American society at large, with some members favoring strong legislation and penalties, while others trusted scientists to regulate their own work, or deferred to local jurisdiction. As a result of these divisions, no law was enacted (Teichmann 1983).

In addition to the biological concerns, secondly, Fredrickson was convinced that no new regulatory machinery, other than RAC, was needed to supervise rDNA research (Frederickson). Scientists, he was convinced, were familiar with and supportive of centralized decision-making by panels of NIH experts. Third, he concluded that in order to gain public support for genetic research and avoid charges of secrecy, RAC deliberations were to be open to the public and their transcripts to be published in Recombinant DNA Research, a multi-volume compilation of correspondence, legislative bills, drafts, and media accounts of the rDNA controversy. Fourth, Fredrickson prevailed upon President Gerald Ford to establish a Federal Interagency Committee on Recombinant DNA Research, with the goal of replacing the uncoordinated approaches of various departments that sponsored rDNA research with a single set of guidelines. Fifth, judging that it was most urgent to allow rDNA research to proceed, Fredrickson decided to issue the guidelines before completion of an Environmental Impact Statement (Frederickson 1982).

The NIH Guidelines were released by Fredrickson on June 23, 1976, an event that made for front-page news, followed in October 1977 by a draft Environmental Impact Statement (Frederickson). Canada and several western European nations agreed to adhere to the guidelines as well (Zilinskas and Zimmerman 1986). Using their regulatory powers, the Food and Drug Administration and other federal agencies compelled the small number of private laboratories then using rDNA technology to abide by the NIH guidelines (Zilinskas and Zimmerman 1986).

A revised set of Guidelines took effect on January 1979, in particular easing containment requirements for rDNA experiments with E. coli after no such experiments had produced harmful side-effects (National Institutes of Health 2013). The revised Guidelines also laid out procedures for ongoing revision, and shifted responsibility for interpretation and enforcement to researchers' home institutions.

The NIH Guidelines remain in force today, and the most controversial research continues to be reviewed by the RAC. No new epidemic pathogen has been inadvertently produced in the course of three decades of rDNA research (National Institutes of Health 2013). The struggle of the participants in the rDNA controversy to find a compromise that would at once preserve scientific freedom, the public's health, and ethical values lays the groundwork to understand the oversight in place today (Frederickson). Genetic manipulation with recombinant and synthetic nucleic acids remain at the center of today's debate over stem cell research, genetic cloning, and genetically modified foods, with the Institutional Biosafety Committee center in the middle of the discussion.

The Role of the Institutional Biosafety Committee and Risk Assessment

The NIH, Office of Biotechnology Activities (OBA) oversees the implementation of the NIH Guidelines through registration, annual updates, and periodic on-site audits of local IBCs (National Institutes of Health 2013). The role of the IBC is to ensure adequate containment of potentially hazardous biological agents; add a level of expert review and monitoring of potentially hazardous experiments; to inform the public about experimental plans that have a potential to be hazardous; and to provide a means of communication among researchers and healthcare provides about potentially hazardous protocols (NIH-OBA 2010).

The fundamental core of IBC review is the concept of a risk assessment of work with biological materials, highlighted in Section IV-B-2-b of the NIH Guidelines (National Institutes of Health 2013). The risk assessment is initiated by a Principal Investigator conducting the research and subsequently reviewed, modified, and subsequently accepted or rejected by the entity's local IBC. The International Biological Threat Reduction Program of Sandia National Laboratories elaborates the biological risk assessment should clearly define the biological risk being assessed and mitigated (Caskey, 2010). Assessment and mitigation methods are a combination of engineering controls, procedure and administrative controls, and the use of personal protective equipment (Caskey, 2010). The NIH Guidelines directly reference the CDC biosafety resource and guidance document, the BMBL 5th edition, in elaborating on the concept of risk assessment (DHHS, 2009) (National Institutes of Health, 2013). The CDC BMBL defines risk assessment as the process used to "identify the hazardous characteristics of a known infectious or potentially infectious agent or material, the activities that can result in exposure to an agent, the likelihood that such exposure will cause a laboratory acquired infection, and the probable consequences of such an infection" (U.S. Department of Health and Human Services, 2009).

The NIH Guidelines outline the risk assessment must take into consideration "virulence, pathogenicity, infectious dose, environmental stability, route of spread, communicability, operations, quantity, availability of vaccine or treatment, and gene product effects such as toxicity, physiological activity, and allergenicity" (National Institutes of Health, 2013). Additional factors such as advances in synthetic biology and genetics may introduce new variables to the assessment of the Risk Group, characteristics, and proposed containment (National Institutes of Health, 2013).

The Institutional Biosafety Committee system and process is not without public criticism. A study by Race and Hammond, highlighted "serious ongoing problems with IBCs' adherence to NIH Guidelines" and called for the abolition of the voluntary governance framework the Institutional Biosafety Committee uses. Race and Hammond argue the current system requires improvement or replacement, citing a survey of institutional practices (Race and Hammond, 2008).

In terms of age as a compliance committee, the non-profit organization, Public Responsibility in Medicine and Research recognizes the three "I"s in research: the Institutional Review Board, or IRB, the Institutional Animal Care and Use Committee, or IACUC, and the IBC (PRIMR, 2010). As far as entity funding and support, PRIM&R recognizes IBCs lacks the support and resources that are in place for IRBs and to some extent IACUCs around the country. The NIH-OBA office through on-site audits and outreach has assisted in bringing awareness of the IBC up to level of awareness by the institution to the IRB and IACUC (Shipp and Patterson, 2003).

To date, surveys by Hackney, et al and others have raised awareness on the current review structure and capabilities of IBCs (Hackney, 2011). The qualitative data obtained from several surveys provides insight into the selected aspects of IBC burdens, including staffing and review process of biological materials, and training.

The Hackney, et al surveys found improvements in IBC management, staffing, and compliance observed over the course of the surveys. For example, Hackney reports that NIH OBA has, since 2001, increased efforts to offer educational conferences and courses for IBC members and those responsible for IBC oversight (Raymond W. Hackney 2011). Because of these efforts, the research compliance workforce is likely to be slightly more educated on the Guidelines than in the past. Second, the NIH OBA established the site visit program, which allows for an in-depth review of the rDNA research oversight structure and practice for an institution. The program review can also reveal a need for additional staff in order to fulfill the IBC responsibilities. Of those respondents to the 2010 survey, 22% of those who reported that they had a site visit at their institution indicated that they had increased funding or staffing as a result of the site visit (Hackney, 2011). Unfortunately, the number of institutions having been through an NIH-OBA site is estimated to be a small percentage from the actual list of registered IBCs with NIH-OBA. Finally, incidents in the news and public scrutiny drew attention to weaknesses in IBC compliance with the Guidelines (Cook-Deegan, Berkelman et al. 2005, Field 2005).

However, the prior surveys by Hackney et al lacks quantitative data on the increasing registration and policy burdens of IBCs over time, as well as on the number of protocol reviews, administrative, resources, and financial support. Other research by Dolgitser on Dual Use, Muller on IBC Quality Improvement, and research by Shine and Chamberlain touch on aspects of Institutional Biosafety Committee and biological materials oversight, but none attempt to address the issue of quantitative burden over time (Muller, Stewart et al., Dolgitser 2007, Chamberlain, Burnett et al. 2009, Shine and St. Onge 2009).

Thus, no other data exists in the scientific literature addressing IBC oversight, burden, and trends. The goal is to obtain data via a cross-sectional survey aspects of IBC composition,

review, support, and administration to provide further knowledge into biological safety and regulatory oversight in relation to biosecurity and public health for entities working with biological materials.

United States Regulatory Oversight of Biological Materials in Research

An extensive federal review of biological materials took place and concluded in 2009, entitled "Report of the Trans Federal Task Force on Optimizing Biosafety and Biocontainment Oversight provides an in-depth review of the current regulatory climate for biological materials (USDA, 2009). The regulatory environment for biological materials research oversight is a patchwork composite from different federal, state, and even local or municipal agencies and organizations (USDA 2009). High containment laboratories at BSL-3 in particular have received increased scrutiny due to their work with Risk Group 3 agents (Kingsbury, 2013). The dominant agencies with oversight over biological materials are the NIH Guidelines for entities receiving NIH funding for rsNA research, and the CDC and USDA for high consequence pathogens and importation concerns, as well as others (USDA 2009). A visual example of biological materials oversight is provided in Figure 1:

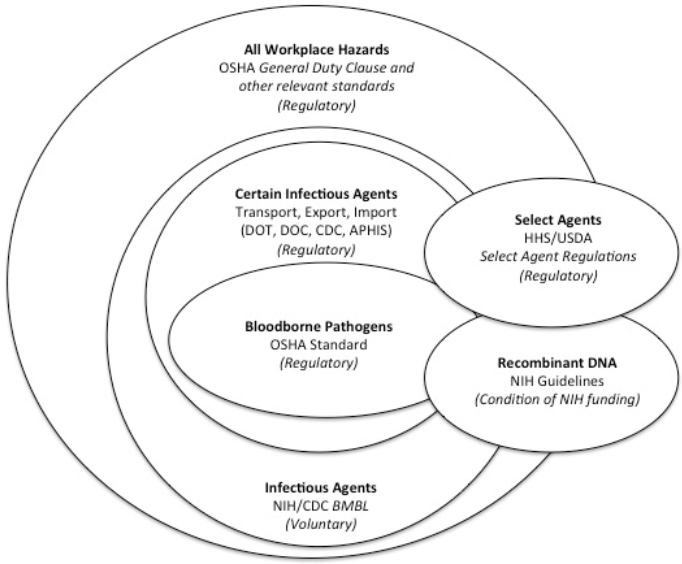

Figure 1. Biosafety/Biocontainment Regulations, Standards, and Guidelines Pertinent to High Containment and Maximum Containment Research (USDA 2009)

As noted in Figure 1, a variety of agencies and regulations touch on various aspects of biological materials oversight in research. The next sections will highlight the major federal regulations and guidelines for biological materials oversight in research.

National Institutes of Health

The Institutional Biosafety Committee is required to be formed and conducts risk assessments for review of rsNA molecule research, if the entity or product given to human subjects receives or received NIH funding for rsNA research in the life sciences (National Institutes of Health, 2013). Otherwise, an institution is not required under any Federal regulation to conduct a risk assessment by a committee of scientific peers on recombinant or wildtype biological materials unless an entity chooses to work with viable organisms on the CDC/USDA Select Agent list, or specific state and municipal are triggered (National Institutes of Health, 2013).

Covered under Section III of the NIH Guidelines are the specific requirements of experiments requiring IBC review (National Institutes of Health, 2013). The experiments range from major actions such as Section III-a-1 where review by the NIH, RAC, and the local IBC is required for research involving the deliberate transfer of a drug resistance trait to microorganisms that are not known to acquire the trait naturally (National Institutes of Health, 2013). With advances in gene therapy, IBC reviews of human gene therapy utilizing rDNA and rsNA is increasing (National Institutes of Health, 2013). Most research reviewed by the IBC falls under the categories of Section III-D, III-E, and III-F, which involve IBC review prospective of the research, concurrently with the research, or through exemptions by the NIH, exempted from Committee review but registered with the IBC (National Institutes of Health, 2013).

Given the growing threat of the misuse of biomedical research by terrorists or others, entities are likely to encounter research protocols that raise dual-use issues. The National Science Advisory Board for Biosecurity (NSABB) released in 2012 the United States Government Policy for Oversight of Life Sciences Dual Use Research of Concern (National Institutes of Health, 2012). The purpose of this policy is to establish regular review of United States Government funded or conducted research with certain high-consequence pathogens and toxins for its potential to be dual use research of concern (DURC). This policy was enacted specifically to mitigate risks where appropriate, and collect information needed to inform the development of an updated policy, as needed, for the oversight of DURC (National Institutes of Health, 2012).

The challenge with DURC is that all life sciences research can be considered dual use, and thus the policy aimed to pinpoint certain types of experiments where additional conduct and review is warranted (Fauci, 2012). A dual-use committee (DUC), institutional biosafety committee (IBC), or other committee should handle this task and convey its findings and recommendations to institutional officials (Resnik, 2010).

Oversight of human gene transfer research ("gene therapy") presents an important model with potential application to oversight of nanobiology research on human participants (Wolf, Gupta et al. 2009). Gene therapy oversight adds centralized federal review at the National Institutes of Health's Office of Biotechnology Activities and its Recombinant DNA Advisory Committee to standard oversight of human subjects research at the researcher's institution (by the Institutional Review Board and, for some research, the Institutional Biosafety Committee) and at the federal level by the Office for Human Research Protections (National Institutes

of Health, 2013). The Food and Drug Administration's Center for Biologics Evaluation and Research oversees human gene transfer research in parallel, including approval of protocols and regulation of products (Wolf, Gupta et al., 2009).

CDC and USDA/APHIS Select Agent Program

The Centers of Disease Control and United States Department of Agriculture, Agriculture and Health Plant Inspection Service, regulate a list of high-consequence pathogens deemed to possess bioterror weapon characteristics, such as high mortality rate, low LD50, or highly infectious nature (CDC, 2011) (USDA 2011) (USDA 2011). The Federal Select Agent Program is jointly comprised of the Centers for Disease Control and Prevention/Division of Select Agents and Toxins and the Animal and Plant Health Inspection Services/Agricultural Select Agent Program (Pastel, Demmin et al., 2006). The Federal Select Agent Program oversees the possession, use and transfer of biological select agents and toxins, which have the potential to pose a severe threat to public, animal or plant health or to animal or plant products (CDC/USDA, 2013).

The Select Agent Program aims to enhance United States oversight of the safety and security of Select Agents by developing, implementing, and enforcing the Select Agent Regulation, maintaining a national database, inspecting entities that possess, use, or transfer select agents (USDA, 2009). In addition the Program seeks to ensure that all individuals who work with these agents undergo a security risk assessment performed by the Federal Bureau of Investigation/ Criminal Justice Information Service, provide guidance to regulated entities on achieving compliance to the regulations through the development of guidance documents, conducting workshops and webinars, and to investigate any incidents in which non-compliance may have occurred (CDC/USDA, 2013).

The Select Agent regulations are located in found at 42 CFR Part 73, 9 CFR Part 121, and 7 CFR Part 331 (2011, 2011, 2011). The Select Agent Regulations implement the Subtitle A and Subtitle B (also known as the Agricultural Bioterrorism Protection Act of 2002) of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, setting forth the requirements for the possession, use, and transfer of select agents and toxins (2002). The Centers for Disease Control and Preventions' (CDC) Division of Select Agents and Toxins (DSAT) and the Animal and Plant Health Inspection Services' (APHIS) Agricultural Select Agent Program (ASAP) jointly constitute the Federal Select Agent Program (USDA 2009).

A subset of select agents and toxins have been designated as Tier 1 because these biological agents and toxins present the greatest risk of deliberate misuse with significant potential for mass casualties or devastating effect to the economy, critical infrastructure, or public confidence, and pose a severe threat to public health and safety (Obama 2010, Avalos 2012).

In determining whether to include an agent or toxin on the HHS select agent list, the Public Health Security and Bioterrorism Preparedness and Response Act requires several criteria be considered, including the effect on human health of exposure to the agent or toxin, the degree of contagiousness of the agent or toxin and the methods by which the agent or toxin is transferred

to humans and the availability and effectiveness of pharmacotherapies and immunizations to treat and prevent any illness resulting from infection by the agent or toxin (DHHS, 2002). In addition, other criteria, including the needs of children and other vulnerable populations is also considered (DHHS, 2002).

For the USDA determinations, in determining whether to include an agent or toxin on the USDA list, the Agricultural Bioterrorism Protection Act of 2002 requires consideration of the effect of exposure to the agent or the toxin on animal and plant health, and on the production and marketability of animal or plant products, the pathogenicity of the agent or the toxin and the methods by which the agent or toxin is transferred to animals or plants, and the availability and effectiveness of pharmacotherapies and prophylaxis to treat and prevent any illness or disease caused by the agent or toxin (Avalos 2012). In addition, any other criteria that the Secretary considers appropriate to protect animal or plant health, or animal or plant products (2005). The lists are required to be reviewed and republished every 2 years, or revised as necessary (Avalos 2012).

The Intragovernmental Select Agents and Toxins Technical Advisory Committee (ISATTAC) is an inter-agency workgroup of subject matter experts from Federal government Departments and Agencies constituted by the CDC Director to provide recommendations to the Select Agents and Toxins in the following three technical areas: (1) review of requests for the exclusion of attenuated strains, (2) review of requests to conduct restricted experiments, and (3) review of the select agents and toxins listed in Part 73 (National Academies, 2009).

Administrative penalties under the Federal Select Agent Program have the authority to deny, suspend, or revoke registration to use, possess, or transfer select agents and toxins (Preparedness Act, 2002). In addition, the Federal Select Agent Program has the authority to deny an individual access to Select Agents and Toxins to protect public health and safety (Preparedness Act, 2002).

In addition to any other penalties that may apply under law, any person who violates any provision of Select Agent regulations shall be subject to the United States for a civil money penalty in an amount not exceeding $250,000 in the case of an individual and $500,000 in the case of any entity (Preparedness Act, 2002).

Violations of 18 USC 175b, a "restricted person" that possesses a select agent or toxin, or transfers select agent or toxin in interstate or foreign commerce, (and is not excluded or exempted under select agent regulations) is subject to a criminal fine, imprisoned not more than 10 years, or both (Preparedness Act, 2002).

Whoever transfers a Select Agent or Toxin to a person who the transfer or knows or has reasonable cause to believe is not registered with the Federal Select Agent Program in accordance with the Select Agent regulations is subject to a criminal fine or imprisoned for not more than 5 years, or both (Preparedness Act, 2002). Whoever knowingly possesses a Select Agent or Toxin when that person is not registered with the Federal Select Agent Program in accordance with the Select Agent regulations is subject to a criminal fine and/or imprisoned for not more than 5 years (Preparedness Act, 2002).

Occupational Safety and Health Administration

More than 500,000 workers are employed in laboratories in the U.S. Laboratory workers exposed to numerous potential hazards including chemical, biological, physical and radioactive hazards, as well as musculoskeletal stresses fall under various oversight by OSHA (Roy 2000). Laboratory safety is governed by numerous local, state and federal regulations (Azmi Mohd and Norafneeza). Over the years, OSHA has promulgated rules and published guidance to make laboratories increasingly safe for personnel (Krienitz). There are several primary OSHA standards that apply to laboratories as well as other OSHA standards that apply to various aspects of laboratory activities, including OSHA Bloodborne Pathogens and OSHA Hazard Communication (Kuruvilla 2010, 2011, Traynor 2012).

Additional OSHA standards provide rules that protect workers in laboratories from chemical hazards as well as biological, physical and safety hazards. Occupational Exposure to Hazardous Chemicals in Laboratories standard was created specifically for non-production laboratories (Kenison 1994) For those hazards that are not covered by a specific OSHA standard, OSHA often provides guidance on protecting workers from these hazards under the Hazard Communication Standard (Traynor 2012).

Although the OSHA standards discussed deal specifically with laboratories within the jurisdiction of Federal OSHA, there are twenty-five states and two U.S. Territories (Puerto Rico and the Virgin Islands) that have their own OSHA-approved occupational safety and health standards, which may be different from federal standards, but must be at least "as effective as" the federal standards These state-OSHA plans must meet the minimum criteria laid out in the Federal OSHA standard, and typically are more stringent than the Federal OSHA (USDA 2009) (USDA 2009).

In addition, the OSHA Bloodborne pathogens are infectious microorganisms in human blood that can cause disease in humans (Cuny and Fredekind 2002). These pathogens include, but are not limited to, hepatitis B (HBV), hepatitis C (HCV) and human immunodeficiency virus (HIV) (Narin, Gedik et al. 2012). Needlesticks and other sharps-related injuries may expose workers to bloodborne pathogens (Marini, Giangregorio et al. 2004). Workers in many occupations, including research laboratories and support staff, may be at risk of exposure to bloodborne pathogens (Buesching, Neff et al. 1989).

Food and Drug Administration, Center for Biologics Evaluation and Research

The Center for Biologics Evaluation and Research (CBER) regulates cellular therapy products, human gene therapy products, and certain devices related to cell and gene therapy (Gruber 2011). CBER uses both the Public Health Service Act and the Federal Food Drug and Cosmetic Act as enabling statutes for oversight (Theresa, 2007, Gruber 2011).

Cellular therapy products include cellular immunotherapies, and other types of both autologous and allogeneic cells for certain therapeutic indications, including adult and embryonic stem cells (Mason, Brindley et al. 2011). Human gene therapy refers to products that introduce

genetic material into a person's DNA to replace faulty or missing genetic material, thus treating a disease or abnormal medical condition (Friedmann 1972).

Although some cellular therapy products have been approved, CBER has not yet approved any human gene therapy product for sale in the United States, although the first therapy was approved in Europe in early 2013 (Wirth, Parker et al. 2013). However, the amount of cellular and gene therapy-related research and development occurring in the United States continues to grow at a fast rate (2009). CBER has received many requests from medical researchers and manufacturers to study cellular and gene therapies and to develop cellular and gene therapy products. In addition to regulatory oversight of clinical studies, CBER provides proactive scientific and regulatory advice to medical researchers and manufacturers in the area of novel product development.

Other Regulatory Oversight of Biological Materials and Summary

In addition to the NIH, CDC/USDA Select Agent Program, OSHA, and FDA, other federal organizations may peripherally regulate aspects of biological materials. Figure 2 provides the framework of United States biosafety and biocontainment oversight for biological materials starting with the Principal Investigator.

The Department of Transportation and Federal Aviation Administration regulate the packaging and transport within the United States (USDA 2009). The Office of Export Controls oversees the transactions of biological to entities beyond U.S. borders. The CDC and USDA have additional divisions to inspect and regulate facilities seeking inter-state or international transport of biological materials into the United States. Municipalities and state legislature

Figure 2. Biosafety and Biocontainment Oversight

such as Cambridge, Massachusetts and the State of California may enact additional regulation on biological materials in life sciences research. A current list of oversight with biological materials is provided as Appendix C from the USDA Report of the Trans-Federal Task Force on Optimizing Biosafety.

Based on the literature review and current described above, this research hypothesizes a survey of current biological materials oversight and regulatory review will highlight gaps in United States federal and local oversight. Next, a review of the methodology to assess this hypothesis is provided.

Materials and Methods

As required by the NIH Guidelines, all institutions are required to register with the NIH Office of Biotechnology Activities for the creation of the IBC. Based off prior research by Hackney and others, assistance of NIH-OBA, and a lack of quantitative data on IBCs, a cross-sectional survey was deemed through the development phase with the scientific dissertation committee to be the appropriate method for approaching the topic of biological materials oversight.

The survey consisted of 28 questions regarding administration of IBC responsibilities, Committee membership and support, and oversight of biological materials, and is listed as Appendix A for the Pilot Survey and Appendix B for the full survey. In order to recruit institutions for a survey on IBC practices, support, and review parameters, two Freedom of Information Act requests by the researcher to the NIH/OBA office was issued. The first FOIA request in August, 2012 under FOIA #40395, resulted in the receipt of an electronic spreadsheet detailing IBC contact information for IBC institutional representatives and biosafety officers (National Institutes of Health, 2012). As of September, 2012, a total of 857 Institutional Biosafety Committees existed in the NIH/OBA records, with 1157 institutional contacts and listed biosafety officers. The data range of the survey begins with the initiation of IBCs in 1976 (coinciding with the inception of the NIH Guidelines) through February 15, 2013; a period spanning close to forty years for some IBCs. After the survey was disseminated, a second FOIA request, #41253 was issued in April, 2013, and a response from NIH-OBA was received in May, 2013, with a spreadsheet total of 866 Institutional Biosafety Committees in the NIH-OBA records (National Institutes of Health, 2013).

In consultation with the researcher's IRB, a human subject's review was determined to be unnecessary as the research focus was institutions and not human subjects.

A pilot study survey was initially distributed to 5% of registered IBCs, followed by an analysis of data for meaningful results, and then distribution of the survey to the remaining 95% of registered IBCs. The Dissertation Committee and literature review of survey responses aimed for a 20% participant response rate for the main survey in order to obtain valid data for statistical analysis. The pilot survey was open for two weeks in December, 2012. Upon

survey closure, interviews were conducted with selected recipients and analysis of the pilot data commenced. The main survey was released January 15th, 2013 to February 15th, 2013. Survey distribution was conducted using Qualtrics© survey software available for the School of Public Health at Saint Louis University Graduate School (Qualtrics, Provo, UT) via e-mail. Reminders to survey recipients were sent via e-mail at the two week and four week intervals. For both the pilot and main surveys, institutional responses were kept confidential, and the survey results reported only in aggregate, as the population of institutions that responded to the survey. The statistical analysis package used was SPSS 19 (IBM).

Institutional Recruitment

In FOIA request #40395, NIH-OBA provided the institution name, first and last name of the primary IBC contact, phone number, and e-mail address as required for registering the IBC with NIH-OBA. In addition, for institutions with rsNA research requiring a Biosafety Officer, contact information in the same format was provided. From FOIA #40395, the initial pilot survey institutions were chosen randomly using the SPSS 19 software package. Of the 40 pilot survey institutions, 7 of the pilot institutions contact e-mail addresses were unable to be delivered, due to incorrect contact information provided by NIH-OBA.

Due to the size and ease for which contact information, the remaining 817 institutions listed under the NIH-OBA FOIA request #40395 were contacted with a survey request by electronic mail on January 15th, 2013. Another 43 institutions from the NIH-OBA list did not have correct contact information from the entity in order for the survey to reach the institutional representatives for the IBC. FOIA request #41253 in May, 2013 noted an increase in IBCS by 9 IBCs.

Demographics of the Population

Most entities receiving NIH funding tend to be academic in nature, although other entities include private commercial ventures, non-profit research institutions, government entities, and other bodies including hospitals and clinics. A lack of identifiable information by NIH-OBA from the FOIA requests did not allow for a pre-survey assessment of the demographics of the types of entities registered with NIH-OBA. In addition, while many entities do not receive NIH funding for rDNA or rsNA research, NIH-OBA encourages and entities voluntarily register an IBC with NIH-OBA if work is conducted with rDNA or rsNA as a life sciences industry best practice.

The survey itself sought to establish the demographics of the entities registered in order to ascertain support inferences from additional information on practices and institutional support, in addition to the type of biological materials research under review at the institution.

For the purposes of the survey, an institution is an entity that is distinct to require a registered IBC.

Results

Initial Results

Upon closure of the survey February 15, 2013, main survey resulted in responses from 181/817 institutions, for a total of 21.2% response rate, including 49 partially completed surveys. Another 49 surveys were started but were not submitted. This is in addition to 13/40 out of the initial pilot survey, for a 32.5% response rate for a total of 194/857 complete responses, and 22.6% response rate overall. For the purposes of the tabulated research results, the main survey consists of 181 responses, 132 responses with all questions answers and the 49 partially completed surveys, were used for cross-tabulation and statistical analysis.

Biological Materials Oversight

From the main survey, 172/173 (99.4%) Institutional Biosafety Committees who registered with the NIH-OBA review rsNA. 109/173 IBCs review whole microorganisms, 103/173 review work with OSHA Bloodborne Pathogens, 94/173 work with biological toxins, 56/173 Dual Use Research of Concern (DURC), and 20/173 indicated other, for field releases. This information is presented in Table 1.

	Small University	Medium University	Large University	Research Institute	Private Industry	Government	Non-Profit	Other	Total
rsNA	18	35	59	17	11	8	13	11	172
Microorganisms	11	24	43	8	2	5	8	8	109
OSHA BBP	10	22	37	13	3	5	5	8	103
Biological Toxins	8	18	41	9	2	6	3	7	94
Select Agents	10	20	40	7	2	5	2	7	93
DURC	2	9	30	5	0	2	3	5	56
Other	1	4	9	1	1	1	0	3	20
Total	18	35	59	17	11	9	13	11	173
Chi-Square: 53.18	Df: 28	p-value: 0.00							

Table 1. IBC Survey Cross-Tab - Institution Type by Type of Biological Materials Research

Of the 172 entities reviewing rsNA, 156/172 (91%) review laboratory benchtop projects, 124/172 (72%) animal research with rsNA, 67/172 (39%) review rsNA with plant materials, 58/172 (34%) review gene therapy or pre-clinical vaccine work, and 10/172 (6%) indicated other categories not asked in the survey question. This information is presented in Table 2.

	Small University	Medium University	Large University	Research Institute	Private Industry	Govern ment	Non-Profit	Other	Total
Lab Benchtop	18	31	60	15	7	7	10	8	156
Animal	13	26	51	14	3	3	6	8	124
Plant	7	11	42	2	2	0	2	1	67
Gene Therapy	6	12	15	3	3	3	3	9	54
Other	0	2	4	0	1	0	2	1	10
Total	18	34	60	17	11	8	13	11	172
Chi-Square: 53.18	Df: 28	p-value: 0.00							

Table 2. IBC Survey Cross-Tab - Institution Type by Categories of Recombinant DNA Review

Also of interest is the frequency for which entities review biological materials, and the length of time of IBC Protocol duration are addressed in Tables 3 and 4, respectively. The most common meeting schedules were monthly, 69/174 (40%), and as needed, 51/174 (31%). The most frequenty type of protocol review schedule was annually, with 69/174 (40%) institutions, and triannually 66/174 (38%).

	Small University	Medium University	Large University	Research Institute	Private Industry	Govern ment	Non-Profit	Other	Total
As needed	5	11	14	5	7	3	5	1	51
Annually	1	4	4	1	4	0	1	1	16
Quarterly	3	6	3	3	0	3	6	1	25
Bi-monthly	1	1	3	2	0	0	1	1	9
Monthly	7	10	35	6	0	3	3	5	69
Other	4	7	2	2	0	1	0	2	18
Total	17	35	60	17	11	9	14	11	174
Chi-Square: 43.02	Df: 28	p-value: 0.03							

Table 3. Institution Type by IBC Meeting Frequency

	Small University	Medium University	Large University	Research Institute	Private Industry	Govern ment	Non-Profit	Other	Total
Annual (Every Year) Renewal	10	14	14	2	8	6	9	6	69
Bi-Annual (Every 2 Years) Renewal	1	0	3	0	0	0	0	0	4
Tri-Annual (Every 3 years) Renewal	4	15	29	10	0	2	2	4	66
One-time with approval indefinite	1	2	5	1	2	1	0	0	12
Other	6	4	14	4	1	0	3	2	34
Total	18	34	60	17	11	9	14	11	174
Chi-Square: 43.02	Df: 28	p-value: 0.03							

Table 4. Institution Type by IBC Protocol Duration

Institutional Support

162/173 (94%) of the entities internally reviewed and administered the IBC to review work with rsNA, with 11/173 (6%) of institutions electing to utilize external sources for IBC administration. Most entities elected to staff with the minimally required two community members (160/173), although several entities indicated a need to have additional members on the Committee in case quorum could not be reached (13/173). 33/139 (24%) of IBCs compensated the IBC Chair for time spent running the Committee, and 7/128 (5%) compensated IBC members for time spent on the Committee. These items are addressed in Tables 5 and 6.

	Small University	Medium University	Large University	Research Institute	Private Industry	Govern ment	Non-Profit	Other	Total
Yes	2	7	14	1	1	3	1	4	33
No	14	21	36	10	8	4	9	4	106
Total	16	28	50	11	9	7	10	8	139
Chi-Square: 17.71	Df: 14	p-value: 0.22							

Table 5. IBC Survey Cross-Tab - Institution Type by IBC Chair Compensation

	Small University	Medium University	Large University	Research Institute	Private Industry	Government	Non-Profit	Other	Total
Yes	1	0	2	1	0	1	2	0	7
No	15	25	43	12	7	6	6	7	121
Total	16	25	45	13	7	7	8	7	128
Chi-Square: 9.45	Df: 7	p-value: 0.22							

Table 6. IBC Survey Cross-Tab - Institution Type by IBC Members Compensation

Review and Approval Process

The next set of questions dealt with the review and approval process. Respondents approached the survey question on "Estimated Time for Review per Protocol) in two different methods. One method calculated the actual time spent reviewing the project in minutes. The other method saw responses from initial receipt of the project, to actual time of IBC review of approval in days.

The average length of time for 105 responses in hours of review by the biosafety officer and administrative support, starting with receipt of the IBC protocol from a researcher to a convened meeting, involving pre-review, inspection, and back-and-forth feedback to a PI, was 5.2 hours per protocol. Several respondents noted two types of review, human gene transfer and high containment reviews at BSL-3/BSL-4, would require significantly more time and should not be included. 49 responses indicated the length of time from receipt to IBC approval in days, to be an average of 29 days, with a minimum of 7 days to a maximum of 90 days for IBC review.

Case Studies of Research by Year

Twenty-two entities provided a year by year summary of IBC registered protocols and research. This data is represented in Figure 3.

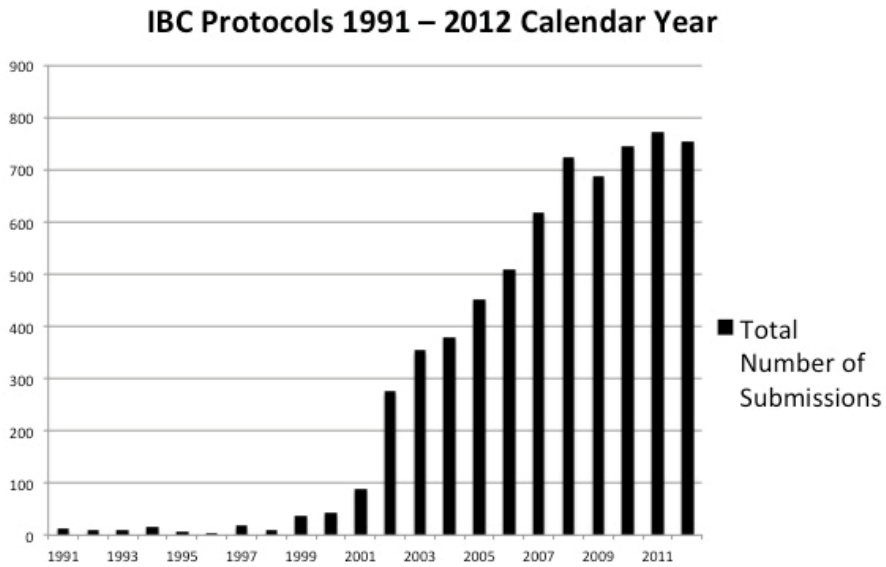

Figure 3. IBC Protocals 1991-2012 Calendar Year Case Study

In addition, data obtained from the two FOIA requests in addition to data from previous FOIA requests show the increase in the number of registered IBCs started with 56 in 1976, to 886 in 2013. This is shown in Figure 4.

Responder Comments

The survey provided an opportunity for biosafety professionals to raise concerns concerning the field of biological materials oversight. These anecdotal responses help to shed light on the current state of support for the IBC and biological safety program at the entity.

Responses indicated a lack of institutional support for both financial support as well as staffing in order to even maintain a database of past and current IBC protocols. Other statements in free form from responders commented on recombinant DNA being remarkably safe, and the real issues of biological materials oversight with whole microorganisms at Biosafety Level 1 and Biosafety Level 2. Another area of expressed concern was over the implementation of the Dual Use Research of Concern and how that would be accomplished at the local entity level.

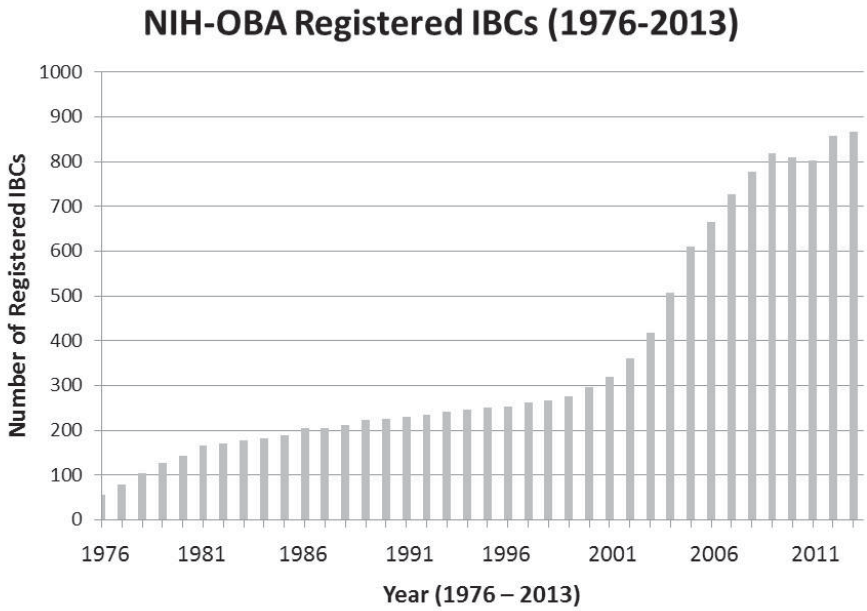

Figure 4. Number of Institutional Biosafety Committees Registered By Year

Discussion

Observed Trends in Biological Materials Oversight and IBCs

Several items regarding biological materials review and support can be inferred from the results of the survey. First, basic research in the life sciences involving biological materials is increasing. This is evidenced by the increasing number of registered IBCs from the Hackney surveys to this cross-sectional survey, and the case-studies of protocols reviewed by year. Second, the IBC is not currently supported with resources for the IBC to function. As currently structured at the majority of institutions, financial and staffing resources are little to non-existent. The most common support is financial compensation for the IBC chair, and a quarter of time allotment for an administrative staff member to assist the Biosafety Officer in running the IBC.

Another finding is institutions are expanding the role of the IBC to include oversight beyond recombinant materials only, to also include review of whole microorganisms, blood borne pathogens, and biological toxins. In addition, IBCs are tasked with fulfilling federal requirements for the review of new DURC requirements, essentially asking institutions to conduct an analysis of whether a research project should ethically be allowed to proceed.

Another finding of note is multiple institutions have on record more than one IBC to cover different aspects of research. The rationale and actual numbers for doing so are unclear at this time, although the researcher hypothesizes entities segment aspects of research for internal

review and external review by registering multiple IBCs. One example is a mid-size academic entity with a hospital system employing one IBC to conduct biosafety assessments of rsNA laboratory, animal, and plant research, and the other IBC to conduct research of rsNA into human subjects.

Recent deaths from biological materials from a Yersinia *pestis* attenuated strain wild-type Neisseria *meningitis*, and other biological materials highlight the importance of institutional risk assessment on manipulations with biological materials (2011, Erin 2013). Little data exists on laboratory acquired infections, but are believed to be underreported by as much as 80% (Pike 1979). For the safety of the growing field of life sciences, it is imperative institutions and regulators work together to assure safety of staff and the environment against unintended release and exposures.

Of the entities with IBCs, 172/173 reviewed rsNA. This is evidence entities such as small colleges and universities, pharmaceutical companies and non-profits, view developing an IBC as an afterthought due to the lack of regulatory stimulus to create and maintain an IBC.

Until now, this information has not been made public, and is of interest to the biosafety community, regulators, and research scientists to see the increase in biological materials oversight through IBC Registrations.

The Future of United States Biological Materials Oversight in Research

As of this writing, current amendments to the NIH Guidelines for research involving human gene transfer are in the process of public comment and review by NIH-OBA. In addition, the recent H5N1 research highlighted concerns from NSABB into issuing requirements for the review of Dual Use Research of Concern. The CDC and USDA Select Agent Program review additions and subtractions to the Select Agent List on a two-year cycle, and have recently implemented a higher level of regulation with 11 agents known as Tier 1 agents. The list is currently in between review cycles for additions or subtractions.

An interesting developing is the American Biological Safety Association's (ABSA) continued efforts since 2008 to establish a BSL-3 accreditation program, to eventually become a self-sustaining accrediting body. The ABSA Laboratory Accreditation program was developed for United States Biosafety Level (BSL) 3 and animal biosafety level (ABSL)-3 laboratories (ABSA, 2012). The purpose of the ABSA accreditation program is to ensure that biocontainment facilities have in place the necessary practices, procedures, personnel, and equipment to protect people, animals, plants, and the environment and minimize the potential of laboratory associated infections and laboratory accidents (ABSA, 2008). Key factors in the ABSA accreditation process are an objective assessment of the technical competence and quality system of an organization or laboratory as it relates to biohazard management, including personnel training and experience (ABSA, 2011). Accreditation, using relevant local, national and international guidelines, regulations and standards is an effective way of ensuring competence in a comprehensive and uniform manner in laboratories working with biohazards. The accreditation program is voluntary, and an agreement between the entity and the ABSA Accreditation Board will define the scope of the review (ABSA, 2012).

Key components assessed by the accreditation program include components of reviewing the biosafety expertise and training of personnel managing and conducting the research, assessing the adequacy and function of the biosafety management structure supporting the research activities, and determining the adequacy and function of biocontainment measures, including facilities, equipment, practices, and record-keeping systems, in place at the facility that is evaluated (ABSA, 2011).

ABSA accreditation will provide entities recognition of excellence and compliance with high standards that will be important among their peers as well as their organization's management (ABSA, 2012). The ABSA accreditation standards will help facilities that need guidance in generating processes and policies to create a safer environment for their organization, its employees, and for the community (ABSA, 2012). Achieving accreditation will be verification to the organization, the employees, and the community that the organization is taking extra steps to create a safer environment. The ABSA Laboratory Accreditation Program does not supplant any required regulatory inspections (ABSA, 2012).

Limitations of the Study

The study has several limitations. First, most institutions lacked the ability to accurately report prior reviews of biological materials in order to determine changes over time. Of the 183 institutions who responded to the survey request, only 22 (12% of respondents in the 2013 survey) institutions were able to provide yearly totals of protocol reviews. The main reason reported by responders is due to a lack of institutional administrative and information technology support for Institutional Biosafety Committees. Few responders had access to information on whether IBC support lacked, matched or surpassed other research compliance committees such as the IRB and IACUC.

Second, responses were skewed towards academic institutions, with medical institutions under represented. In previous research by Hackney there has a very low response rate (5% in the 2013 survey) to the survey from hospitals and non-profits, an institution type that has increased dramatically in the NIH IBC database population over the last fifteen years (Hackney, et al). Fifty-five hospitals and clinics were registered IBCs in 2002 as compared with 303 in 2010. One of the reasons that may have contributed to the lack of response from these organizations was that a handful of commercial organizations that manage IBCs for the vast majority of registered clinics and hospitals did not respond to the surveys. Many of these hospitals and clinics that are registered with NIH may have a very small number of clinical trials being conducted at their sites that require IBC review. The lack of response from clinics and hospitals and the high response rate from academic institutions (71% of the IBCs that participated in the 2010 survey were from academic institutions compared with 42% in the actual IBC population registered with NIH) suggests that the survey results are more representative of academic IBCs than the IBCs from other types of institutions.

A third limitation is that cross-sectional surveys are known to be the weakest method of capturing data to make inferences on a population. Survey data is generally weak on validity but strong on reliability.

There is a lack of data on the true number of accidents with biological materials, and as detailed by Pike earlier, it is well documented for lab accidents to be under reported (Pike, 1979). The current data set is also difficult to determine the difference between Select Agent incidents and recombinant DNA incidents, and a lack of willingness from institutions to disclose non-recombinant accidents with biological materials.

Conclusion

This survey and previous literature on IBCs registered IBCs operate under an unfunded mandate with little institutional support for conducting risk assessments on biological materials. IBCs only provide a snapshot of all biological materials research reference due to the requirement of NIH funding, and institutions who do not receive NIH funding have no incentive or requirements to register and conduct risk assessments on the handling of whole microorganisms, toxins, and human materials. In addition, the survey highlights the disparities between institutions, and highlights the need for additional staffing, training, and support from institutions and at the federal level. The results suggest that while IBCs at larger institutions and well-funded private entities are following many of the practices required by the NIH-OBA, smaller entities may struggle for funding and administrative support. The results indicate that there may be many IBCs that lack adequate staffing and oversight. Thus, future recommendations are aimed at enhancing biological materials oversight through an expansion of NIH-OBA oversight of the IBC, and expansion of the laboratory reporting requirements to the CDC/USDA, through expansion of the NIH Guidelines applicability beyond NIH funded entities.

Author Information

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Appendix

Institution Type
- Small University (student enrollment of 1-4,999 students)
- Medium University (student enrollment 5,000 to 14,999 students)
- Large University (student enrollment of 15,000 and above)
- Research Institute
- Private Industry
- Government
- Non-Profit
- Other

Type of Biological Materials Research Reviewed by the IBC
- Recombinant DNA (Yes/No)
- Whole Microorganism (non-recombinant) (Yes/No)
- OSHA Bloodborne Pathogens (Yes/No)
- Biological Toxins (Yes/No)
- Select Agents (Yes/No)
- Dual Use Research (Yes/No)

Is your IBC administered internally (support staff on location) or externally? (third-party) (Internal/External)

Number of protocols reviewed over IBC active date range (1976 to 2012)
- At BSL-1
- At BSL-2
- At BSL-3
- At BSL-4

Estimated Time for Review per Protocol (from receipt, processing, inspection, IBC meeting, and follow-up items, approval) (0 hours to indefinite)

What type of renewal strategy is employed upon approval?
- Annual renewal
- Bi-annual renewal
- Tri-annual renewal
- One-time with approval indefinite
- Other

Number of Investigators with Approved Protocols

By year from the inception of the IBC, how many initial protocols are approved each year? (1976 to 2012)

If yes to Recombinant DNA Research, what categories of rDNA research have been reviewed? (Select all that apply)

- Laboratory Benchtop
- Animal
- Plant
- Human Gene Therapy

How often are IBC meetings held?

- As needed
- Annually
- Quarterly
- Bi-monthly
- Monthly
- Other

How many Full-Time Employees support the Institutional Biosafety Committee? (0 to indefinite)

How much financial support does the IBC receive from the Office of Research? ($0 to indefinite)

If yes, is the IBC Chair Compensated for time spent? (Yes/No/N/A)

If yes, are other Committee members compensated for time spent serving on the IBC?

How much financial support does the IRB receive from the Office of Research? ($0 to indefinite)

How much financial support does the IACUC receive from the Office of Research? ($0 to indefinite)

Committee Composition (NIH Roster and Function Support)

Number of scientific members

Number of biological safety professionals

Number of external (public) members

Number of administrative staff

Other members (include title and number)

If known, the number of NIH reported laboratory accidents involving recombinant DNA at the entity from 1976-2012.

Appendix B – Full Survey Questions

Institution Type
- Small University (student enrollment of 1-4,999 students)
- Medium University (student enrollment 5,000 to 14,999 students)
- Large University (student enrollment of 15,000 and above)
- Research Institute
- Private Industry
- Government
- Non-Profit
- Other

Type of Biological Materials Research Reviewed by the IBC
- Recombinant DNA (Yes/No)
- Whole Microorganism (non-recombinant) (Yes/No)
- OSHA Bloodborne Pathogens (Yes/No)
- Biological Toxins (Yes/No)
- Select Agents (Yes/No)
- Dual Use Research (Yes/No)

Is your IBC administered internally (support staff on location) or externally? (third-party) (Internal/External)

Number of protocols reviewed over IBC active date range (1976 to 2012)
- At BSL-1
- At BSL-2
- At BSL-3
- At BSL-4

Estimated Time for Review per Protocol (from receipt, processing, inspection, IBC meeting, and follow-up items, approval) (0 hours to indefinite)

What type of renewal strategy is employed upon approval?
- Annual renewal
- Bi-annual renewal
- Tri-annual renewal
- One-time with approval indefinite
- Other

Number of Investigators with Approved Protocols

By year from the inception of the IBC, how many initial protocols are approved each year? (1976 to 2012)

If yes to Recombinant DNA Research, what categories of rDNA research have been reviewed? (Select all that apply)

- Laboratory Benchtop
- Animal
- Plant
- Human Gene Therapy

How often are IBC meetings held?

- As needed
- Annually
- Quarterly
- Bi-monthly
- Monthly
- Other

How many Full-Time Employees support the Institutional Biosafety Committee? (0 to indefinite)

How much financial support does the IBC receive from the Office of Research? ($0 to indefinite)

If yes, is the IBC Chair Compensated for time spent? (Yes/No/N/A)

If yes, are other Committee members compensated for time spent serving on the IBC?

How much financial support does the IRB receive from the Office of Research? ($0 to indefinite)

How much financial support does the IACUC receive from the Office of Research? ($0 to indefinite)

Committee Composition (NIH Roster and Function Support)

Number of scientific members

Number of biological safety professionals

Number of external (public) members

Number of administrative staff

Other members (include title and number)

If known, the number of NIH reported laboratory accidents involving recombinant DNA at the entity from 1976-2012.

A Qualitative Case Study Exploring the Nature of New Managerialism in UK Higher Education and Its Impact on Individual Academics' Experience of Doing Research

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Abstract: *New Managerialism (NM) has been used as an analytical framework to help understand the changes within the UK Higher Education Sector. This project sought to extend that work by undertaking a case study of an English university. Using the theory of NM, the study combined organisational description, strategic document review and in-depth interviews to qualitatively explore the extent to which research management practices could be considered New Managerialist and their impact on individuals' experiences of doing research. This project discovered that management practices could be characterised by a hybridised version of NM. Impact on individuals related to key themes: research funding; performance measurement; academic freedom and control; fragmented organisation and mixed messages; research culture. It was found that individuals consciously engaged in 'informal' strategies to pursue their own research agendas within 'formal' management frameworks. An implementation gap between strategic plans and operational practices created space for individual autonomy, but led to tensions arising from conflicting values at the level of the organisation, department and individual. It was suggested that further investigation could lead to greater insight into how researchers make sense of their role and work environment and, from a management perspective, how best to motivate and support research work.*

Keywords: *research management, new managerialism, research funding, research culture, academic freedom, strategic planning, operational practices, implementation gap, performance measurement*

Introduction

UK Universities are very different places to work in than they were 30 years ago. The Higher Education Sector within the UK has undergone a major shift in terms of its fundamental role and function within society as well as the mechanisms through which it is delivered. This pace of change continues as the Government increasingly looks to the HE sector to provide innovation, and a skilled workforce, in support of national economic competitiveness (Lambert, 2003; Leitch, 2006; Sainsbury, 2007; DIUS 2008; BIS 2011). What was once a fairly independent sector is now subject to a range of different pressures arising from being situated somewhere in between nationalisation and privatisation (Tight, 2006, p.254).

These developments have been analysed through a New Managerial (NM) framework. The concept of NM was originally developed in the context of changes to the way that governments approached the organisation and delivery of public services. NM suggested that the public sector was organised on the basis of neoliberal ideologies associated with economic competitiveness within a global market place, and that greater efficiency and effectiveness in the delivery of services was sought through the use of management practices derived from the

corporate world (Politt 1990; Clarke & Newman, 2004; Hursh, 2005; Davies et al 2006). Many studies suggested that changing management practices had primarily negative effects on universities and academics (Deem et al, 2000, 2007; Shelley, 2005). This was associated with challenges to the professional position and identity of the academic as well as increased stress, bureaucratisation, marketisation, corporatisation and performance measurement within the academic work environment.

However, the concept of NM itself has been problematised with the suggestion that it has changed over time, and that its application within HE in particular has been either hybridised or is incomplete (Deem et al 2007; Clegg, 2008). In addition, given the negative impacts identified, it is unclear why individual researchers appear to continue their research activity with apparent enthusiasm and success. Moreover, it is unclear how universities seemed to adhere to NM ideologies and practices whilst upholding more traditional academic values and customs. This questions the actual nature of NM in universities and, consequently, how this impacts upon individual academics. Other studies focus more directly on the experience of the individual academic. These studies indicated that academic workers engaged in strategies that enabled them to pursue their own agenda and attain ideals of academic freedom in spite of management regimes (Bennich-Bjorkman, 2007; Archer, 2008; Clegg, 2008, Kolsaker 2008; Akerlind, 2008).

Further exploration was therefore undertaken to try to understand the particular nature of management practices being applied to research activity, and how these practices affected the working lives of university researchers. This article presents a qualitative case study investigating the impact of New Managerialism (NM) on the perceptions and experiences of individual researchers by exploring what it is like to do research work within a selected English university.

New Managerialism in UK Higher Education

New Managerialism

Attempts to define NM have arisen as commentators have sought to understand, describe and explain the changes taking place in the provision of public sector services since the late 1970s. It has been defined as:

- an ideology, legitimizing the development of new organizational forms and relationships;
- a practical ideology of 'being business like' in order to make the new arrangements work. (Clarke & Newman, 2004, p. 32)

The concept of NM therefore seeks firstly to explain the socio-economic and political reasons behind why particular organizational regimes have been developed and, secondly, to describe the ways in which public services are now being delivered.

The NM legitimisation of new organisational forms originated from a view that professional-bureaucratic modes of organisation were inefficient and could not cope with the challenges arising from increasing globalisation (Pollitt, 1990). This provided a context of crisis in which supposedly inevitable forces of globalisation required a fundamental restructuring of public

service provision around a neoliberal ideology of deregulation, privatisation and free market mechanisms (Clarke & Newman, 2004, pp. 8-13; Davies et al, 2006, p. 305; Hursh, 2005, p. 13; Lazeretti & Tavloetti, 2006, p. 32). To achieve restructuring, business-like practices based on a neo-Taylorist view of work were appropriated. Organisations were thought to operate most efficiently by planning ahead, breaking down tasks and allocating responsibilities to find the most efficient way of performing each task (Handy, 1999, p. 21) Work tasks are monitored and controlled to improve productivity, motivating individuals through financial reward (Mullins, 2002, pp. 55-58). Efficiency is thought to be driven by having to meet customer needs within a competitive market place.

NM as a concept and set of practices has not, however, remained static. Early neo-Taylorist versions have been replaced by a neo-technocratic variant (Deem et al, 2007). This is linked to the changing practices associated with New Labour's modernization agenda which moves away from a purely neo-liberal framework. Whilst greater cost-effectiveness using business-like mechanisms is still sought, there has been a movement away from purely market based mechanisms to drive efficiency, to contractual mechanisms and performance measurement through audit (Clarke & Newman, 2004, p. 80). Furthermore, 'consumers' are recast. Not only should they have choice regarding where and how they receive services, but they should be actively involved in determining what services should be provided (Deem et al, 2007, p. 15). This represents a fundamental shift in terms of how the role of public service provision is conceptualised and the relationship between government, public sector organisation and 'consumer'.

However, discussion of the impact of NM in the past has tended to focus on an ideal type (Alford, 1993, p. 136). No ideology or set of management practices is necessarily applied in its entirety and the current version of NM has inherent tensions. Neoliberalism requires self-regulating competitive markets and promotes competitive individualism (Roberts, 2007, p. 360). However, practices associated with neo-technocratic managerialism constrain the market through government intervention (such as standards and reporting) and social inclusion objectives (Hursh, 2005, p. 11). An emphasis on social diversity and regulated standards does not fit with neoliberal ideals. In addition, the introduction of performance management and measurement leads to issues regarding what exactly to measure, whether specific measures are appropriate and how these should be interpreted (Cutler & Waine, 2000, pp. 325-329). Thus neo-technocratic managerialism itself appears to be a hybrid concept trying to merge neoliberal ideals of markets and business-like practices with alternative ideologies associated with social agendas and government controls. These tensions within the NM model question both how, and the extent to which, it impacts on actual service provision and providers.

The Impact of New Managerialism on Higher Education and Academic Workers

Traditionally made up of self-governing state funded organisations, universities have historically been relatively removed from Government influence. However, in spite of a neoliberal advocacy of decentralisation and deregulation, the sector has been brought increasingly closer to Government and is now subject to growing control through a variety of management mechanisms derived from the corporate world. Indeed, the influences of NM thinking can be traced through government initiatives and policies for HE over recent decades and have

resulted in a fundamental change in the role and practices of UK HE. These changes have resulted in a number of pressures. In particular, the increased size of the sector and reduced public funding has created a resourcing crisis and the context in which conditions were 'ripe' for the implementation of NM, mirroring developments in the wider public sector (Pollitt, 1990, p. 28). Analysis of key reforms indicates a number of new managerial practices that are now in evidence within the sector:

- A neoliberal legitimization of organisational forms.
- The need to respond to, and be successful within, a competitive external environment.
- A requirement to conform to external performance indicators.
- An emphasis on income generation.
- The emergence of marketing strategies.
- Increased customer oriented administration.
- Increased bureaucracy.
- Increased performance management and evaluation against outputs.
- Transparent measures of performance.
- Clearer demarcation of teaching and research.
- Concentration of resource in pursuit of efficiency and effectiveness.

In addition, however, universities themselves have appropriated a range of management practices as a way of developing and managing themselves within a changing and increasingly complex environment. In an attempt to understand why these changes have taken place, how universities are now being managed and how this affects people working in universities, the framework of NM has been used.

For instance, Deem et al (2000) examined the extent to which NM was perceived to have permeated the management of UK universities. The findings from this study suggested that the UK higher education system could now be characterized as being highly managerial and bureaucratic, with declining trust, discretion and self-governance by academics. It was found that HE displayed hybridized forms of NM that had variable impact. They posit that UK universities and British Higher Education policy are now driven by neo-technocratic managerialism, and that 'institutionalized distrust' has replaced 'regulated autonomy' as the key co-ordinating principle (Deem et al 2007, p. 189). Beyond the UK, other commentators have noted similar trends. For example, Robinson (2009) suggests that 'academic capitalism' increasingly prevails in academic science in the US with the result that researchers are adopting progressively managerial work styles (conforming to industrial norms), and academic freedom and autonomy are being eroded by revenue generation imperatives. Moreover, it is suggested that an emerging tension between opposing academic values (into which scientists are socialized) and capitalist values (to which scientists are pressurised to confirm) becomes a source of tension for the individual.

Other studies such as Shelley (2005) aimed to provide a commentary on work in universities in order to discover 'the reality' of work for staff and to examine how managers and staff respond to the situations in which they work. Shelley suggested that 'cost reduction and more efficient

exploitation of labour may be the real agenda behind the use of marketised, competitive and customer-based control strategies' (Shelley, 2005, p. 69). He concluded that there was a 'staffing crisis' within HE which resulted from work being more bureaucratic and routinised, high workloads and inequality, lack of recognition, reward and equity in performance management and career development opportunities (Shelley, 2005, p. 222).

The findings of such studies portray a bleak view of HE resulting from increasingly managerial practices at policy, sector and institutional level. This is also mirrored in the sector's press, which tends to focus on stress, over-work, administrative burdens and a range of negative impacts arising from NM practices (Baker, 2007). Nevertheless, criticisms have been leveled at earlier studies looking at the influence of NM within HE. For instance, there can be a tendency to contrast current practices with a more 'golden age' that has now passed. However, it has been suggested that clear space for research, free from bureaucratic, political or funding pressures has always been a dream, never a reality, and so the university of the past should not be romanticised (Roberts, 2007, p. 362). Furthermore, it has been posited that the traditional, now lamented, academic identity associated with collegiality and autonomy was never shared equally by all, but emerged from elite positions whose bearers were 'mostly white, male and middle class' (Clegg, 2008, p. 331). In addition, detractors of NM related practices have been criticised for ignoring the 'outside world and the need for strategic change and institutional positioning' (Dearlove, 2002, p. 258). As an alternative, it has been argued that in increasingly turbulent and differentiated environments in which universities now operate, it is essential that they are able to position themselves proactively and act strategically in a way not possible under traditional styles of university management (Meyer, 2002). Some studies of the 'modern' neo-liberal university have also concluded in a more balanced way that whilst there has been considerable change, both old and new systems of governance maintain their own advantages, disadvantages, inefficiencies and systemic faults (Davies et al, 2006).

Clearly, there are a range of differing views about the affects of NM on today's universities. Nevertheless, there is broad agreement about the neoliberal underpinnings and corporate practices that are now associated with the management of universities. What is not so clear is the impact on individuals working within universities. Larger scale studies have tended to explore the system level, thus capturing the 'public' rather than 'private' lives of universities (Trowler, 1998 p. 147). Smaller in-depth studies have developed more nuanced conclusions relating to the impact of NM.

Davies et al (2006) found that academic workers were very aware of the state of financial crisis their universities were in, were concerned about the corporatisation of universities which they felt was forcing them to do inferior work, and often felt under considerable stress particularly given the increased bureaucratic workloads associated with audits. This would agree with the findings of Deem et al (2000) and Shelley (2005). But, in spite of this, they talked about academic work as a reward in itself and often worked long hours to achieve their own intellectual objectives (Davies et al, 2006). In the same way, all interviewees taking part in recent study on academic identities 'spoke with great passion about one or more aspect of their work' (Clegg, 2008, p. 335). Participants were aware of, and regretted, the changes happening

around them, and had a sense that university values were being eroded by marketisation and enterprise. However, they continued to 'act in accordance with their own values' (Clegg, 2008 p. 340). Thus, the suggestion is that whilst the organisational context is by nature managerial, individuals are continuing to maintain an alternative academic value system. Clegg (2008) suggested that this could explain how universities continue to operate in spite of the conditions bemoaned within the literature.

Similarly, in a study looking at academic professionalism, Kolsaker has emphasised that whilst there is evidence that universities are becoming increasingly managerialist, there continues to be debate concerning the extent to which this has displaced collegiality. She asks whether academics have actually lost power and authority, or whether managerialism has 'simply changed the ways in which power is exercised in English universities today' (2008, pp. 515-516). The suggestion here is that whilst critics might 'decry the "corporatisation" of universities . . .the pragmatist might be less concerned' (Kolsaker, 2008, p. 515). The findings suggest that academics are making sense of, and adapting to the changing environment, whilst retaining their professional identity (Kolsaker, 2008, p. 523).

This is illustrated by a study looking specifically at academic freedom for researchers. It is often claimed that managerialism curtails individual academic freedom. However, it has been suggested that what is most interesting in the context of these changes is 'how the researchers themselves view the possibilities open to them of attaining the ideal' of academic freedom (Bennich-Bjorkman, 2007, p. 335). This study concluded that:

- all researchers attributed great importance to the norm of academic freedom which was defined primarily as being able to choose their own research problems;
- interviewees did not feel subject to direct control, but felt they enjoyed the freedom to choose themselves;
- a major preoccupation of their work life related to research funding.

Therefore, whilst NM did have an impact on them and their research work, they still felt they enjoyed academic freedom. It was argued here that they were more likely to have 'negative' freedom (freedom to be left alone) instead of 'positive' freedom to do whatever they want primarily because of the exigencies of the research funding system (Bennich-Bjorkman 2007, p. 345). However, it was not assumed that researchers were passive recipients of change. Instead, they developed 'resistance tactics' to provide them with space to follow their own areas of interest in spite of having to meet funders' specifications, there was in effect a 'double book-keeping' and dexterity in 'packaging research depending on the audience' (Bennich-Bjorkman 2007, pp. 351-356). In much the same way as suggested by Kolsaker (2008), the key idea is that individuals adapt their actions to achieve their goals within the particular management practices of their work environment.

The different conclusions arising from these various studies suggest two areas of caution. Firstly, a linear relationship should not be assumed between management strategies and objectives with individual behaviour. As the studies above indicate, a passive model of academic response to change should not be assumed. Responses to management changes have been shown to

range from compliance, resistance, coping strategies through to 'attempts to reconstruct the policy during the implementation stage' (Trowler, 1998, p. 153). Intended policies can thus actually change when they are delivered. Furthermore, strategic plans tend to be stronger on intention than planning, particularly in organisations like universities where 'bureaucratic and top down authority is weak in a consent-based organisation of professional employees' (Dearlove, 2002, p. 266). Consequently, even if the sector or a university could be described as new managerial, this does not mean that individuals necessarily act in ways dictated by its ideologies and practices. This leads to the second point of caution which relates to the need to be aware of the 'line of sight' into an organisation. The distinction between the 'public' and 'private' lives of a university (Trowler, 1998) hints at the informal and formal levels of an organisation (Appendix 1, Figure 3). The perspective taken will influence the kind of findings that arise. Assessing policies and practices at the formal level are likely to give rise to different perspectives from an assessment of the informal level.

Discussion of studies considering the impact of NM on HE has indicated a complex interaction between academics and their work environment. There is broad agreement that NM and its neoliberal underpinning are apparent within the sector and individual universities, and that current management practices can be explained and understood by recourse to both the ideology and practices of NM. However, the concept of NM has inherent tensions. Moreover, understanding the extent to which university management practices are 'purely' NM, and how they impact upon individuals, is less clear. There has also been limited discussion of this in regard to research work in particular. The following study was intended to address those gaps.

Research Methods

This project employed a qualitative case study method. The main purpose of a case study is not to understand other cases, or to identify 'typical' findings and generalise results. Instead, the purpose is to maximise what can be learned about the specific case under investigation (Stake, 1995). It is concerned with the 'complexity and particular nature of the case in question' and a single case can lead to in-depth findings (Bryman, 2001, p. 47). Furthermore, this methodology is particularly appropriate when: the key research questions focuses on 'how and why'; the researcher has little or no control over behavioural events; and, the focus is on a 'contemporary phenomenon within some real-life context' (Yin, 1994, pp. 1-3). It provides an opportunity to describe the context for the particular case and explore individual perceptions and experiences within that case to build a complex and holistic picture (Cresswell, 1998, p. 15). The objectives were to:

- Provide an overview of the concept of New Managerialism (NM) and consider its impact within Higher Education (HE).
- Describe the case study university and use semi-structured interviews to gather 'insider' accounts to ascertain and describe participants' understandings, perceptions and experiences of doing research.
- Consider the impact of research related management practices and policies on the experience of individual researchers and the delivery of research.

The Case

The 'case' was an English Higher Education Institution (HEI) given the pseudonym 'Mears'. The choice of institution for the case study was primarily intrinsic (Stake, 1995, p. 3) resulting from an interest in finding out more about the specific workings of researchers within this University in the current climate of changing research management practices. The university was also, however, an exemplifying case in that it shared characteristics with other similar organisations and could be taken as a suitable context for researching this particular issue (Bryman, 2001, p. 56).

Secondary Data Collection

A case study usually involves the collection of a wide range of data: documentation, archival records, interviews, direct and participant observations and physical artefacts (Cresswell, 1998, p. 63). Given the scope of this study, it was decided to limit the data to documentation (strategies, written policies and procedures) to enable an assessment of the stated research management practices at various institutional levels. The review targeted current strategies (not historical) to explore the 'here and now' as fits the case study method (Yin, 2003, p. 5).

To consider the University's formal management practices, it was decided to target corporate strategies and related action plans that describe an organisation's 'sense of purpose' and its map for the future direction against which resources can be allocated (Lynch, 2000, p. 7). Such documents convey a strong statement about how an organisation's leaders view its purpose and identity, and how they want it to be viewed by others. Those strategies most directly linked to research activity were identified:

- University Research Strategy;
- University Knowledge Transfer (KT) Strategy;
- Strategies of individuals Departments within the University from which participants were recruited.

Primary Data Collection

Semi-structured interviews were used as they are particularly suited to exploring the specific stories and understandings of participants (Arksey & Knight, 2007, p. 34). It enabled the interviewer to guide discussion towards particular areas of interest, but also to allow interviewees to raise their own views and issues. In addition, unstructured follow up questions were used to enable participants to provide further elaborations and to check meanings (Akerlind, 2008). This also allowed for constant comparison between the data and concepts being developed to support rigor and minimise research bias (Bryman, 2001, p. 542). The aim throughout each interview was to enable participants to discuss their views and experiences of the issues under discussion.

Data Sample

The target interviewees were employees in permanent positions on the academic staff. Individuals were purposively sampled on the basis of existing contacts and snowballing from

interviews. This allowed for selection of participants on the basis of emerging concepts, and to obtain rich and thick data as well as maximum variation to gain multiple perspectives (Cresswell, 1998, p. 120). Specific categories were used to inform participant selection.

Work Role

The scope of this research was specifically focused on those categories of staff able to develop and pursue their own research agenda within their existing academic post. The category of 'academic' was therefore further refined into: academic lecturers, readers or professors. These categories of staff have teaching, research and administrative responsibilities. They are usually in a position to develop their own areas of research which inform their teaching programmes. They may work in isolation, the 'lone scholar', or be members of and/or lead a research team. They are able to apply for funds to develop new research projects, to develop their own research projects, agendas and teams. These responsibilities were identified in the University's generic role profiles. They were intentionally distinguished from contract researchers who are on fixed contracts and are engaged to work on specific research projects, usually externally funded. Such researchers tend to be less well integrated into the academic management structures and are less likely to be able to set their own research agendas outside of the particular project(s) on which they are working. Some of the participants were in a research management position. Research has already been undertaken looking at the emerging role of 'academic managers', why academics take up these roles, what they do in these roles, their experiences and interactions with others (Deem et al, 2007). It was not intended to replicate that here. However, it was expected that position within the organisation's management structure might be significant for individuals' experiences.

Career Stage

Participants were recruited from varying career stages as it was expected that experiences would be affected by their length of time in post and/or in the sector.

- early career – one to five years
- mid-career – six to fifteen years
- advanced – more than fifteen years

Academic Department

This had not originally been a recruitment criterion. However, during the first few interviews, it soon became apparent that it would be important to recruit interviewees from different Departments. It was clear that individuals' experiences varied significantly depending on the Department in which they were based. In effect, they seemed to represent different 'organisations' within the University. Each Department has its own senior management team, strategies and culture. This appeared to affect not only the management framework within which the academic works, but also their perception of what it was like to work within the University.

Discipline

In recognition of the centrality of discipline to an academic's identity and experience of work, participants were recruited from different disciplines. In her discussion on 'becoming an academic', Henkel divides her discussion between 'science' and 'humanities and social sciences' on the basis that sciences have traditionally had a more progressive and structured career structure, whilst humanities and social sciences have tended to be a more casualised labour force (2000, pp. 169-170). Additionally, the Research Excellence Framework (REF) divides discussion of research between Science, Technology, Engineering and Mathematics (STEM) subjects and the arts and social sciences (SSH). To avoid any possibility of being able to identify individuals in the study, this broad disciplinary distinction was used instead of specific disciplines.

Gender

Deem notes that 'knowledge work and knowledge management have some unexpected dimensions in respect of gender' (2007, p. 91). Although the focus of this study was not specifically on gender, it was felt that gender related issues might affect individuals' experiences and their interaction with management systems and processes. Six males and four females were therefore recruited.

Data Collection Process

A pilot interview was undertaken to identify any problems with the interview schedule and process. During the pilot, the following issues were identified:

- questions which were unclear;
- problems relating to the flow of topics being discussed;
- issues relating to the interview process itself.

The interview schedule was revised after the pilot. After each interview, a contact summary sheet (Miles & Huberman, 1994, p. 51) was completed to note any particular issues or considerations which arose during the interview, and any points of interest with regards to analytical notes, or questions to be included in future interviews. A diary was also kept throughout the process for noting any key thoughts, questions, decisions which fed into the data collection and analysis process, and to facilitate reflexivity. Each interview was transcribed verbatim and then checked for accuracy. Transcripts were coded and data transferred into a matrix for thematic analysis.

Data Analysis

Secondary Data

A framework of NM within HE was established on the basis of an assessment. The strategy documents selected were then qualitatively analysed, searching for the key underlying themes which fell within or outside this framework (Bryman, 2001

p. 529). Outcomes were summarised in a table to give an overview of the extent to which selected policies could be considered to be new managerialist.

Primary Data

The intention behind the interviews had been to gather information on individuals' perceptions and experiences of management practices which relate to their research work. Data for each interview was sorted against the themes and sub-themes arising inductively from the empirical data (Miles & Huberman, 1994, p. 65). At each interview, additional themes were identified as necessary and earlier interviews revisited to identify whether there was additional material there relating to new themes. This information was sorted using a thematic matrix. In addition, data sorting and analysis was tested by a second academic using inter-coding comparison to test analysis and support reliability (Miles & Huberman, 1994).

As an intrinsic case study, it was decided to follow the analytical stages expounded by Stake (1995). This involved noting any *direct interpretations* of meaning arising from individual instances and then establishing any *patterns* (categorical aggregation) where there may be a correspondence between two or more categories, and correspondence between interviewees. Subsequently, any naturalistic generalisations which could be learnt about the case study were identified (Cresswell, 1998, p. 154). These are generalisations which are identified in relation to the case rather than ones which may necessarily be transferred to other cases. The idea here is that people receive generalisations (or conclusions) from their own knowledge and others' experience (Stake, 1995, p. 85). The conclusions drawn by the researcher in relation to this case would allow the reader to gain insight into the specific case and also to associate this with their own knowledge or experience. Where possible, quotes from the interviews have been included to try to give interviewees a 'voice' and minimise researcher impact.

Ethics

The researcher followed the British Sociological Association (BSA) statement of ethical practice (2002). The study received ethical approval from both the Open University (OU) and the Ethics Committee of the case study organisation ensuring appropriate research governance. Based on the BSA (2002) provisions, the project was designed to meet requirements relating to informed consent for participants, ensuring privacy and confidentiality, avoiding any potential harm to participants, and meeting data protection provisions.

Results

Documentary Review

A thematic review of the University's Research and Knowledge Transfer (KT) and selected Department strategies was undertaken to identify the extent to which they could be characterised as New Managerialist. The findings of this review related to the legitimisation of organisational forms and use of 'business-like' practices and are presented here.

'Business-like' practice	Research Strategy	KT Strategy	Dept Engineering	Dept Health	Dept Information Systems	Dept Sport	Dept Social Sciences
Operating in a competitive external environment							
Increased internal competition							
Requirement to conform to external performance indicators							
Emphasis on income generation							
Use of marketing strategies							
Increased customer orientation							
Performance management – evaluation against output							
Clearer demarcation of teaching and research							
Concentration of resources in pursuit of efficiency and effectiveness							

strongly referenced
referenced
weakly referenced
not referenced

Figure 1. Summary Findings - Review of Research Related Strategies

Legitimising organisational forms

These strategies posit a need for change within a global, competitive economy. Organisational forms are legitimated by presenting them as the only way to respond to political and socio-economic changes and the resulting challenges they present to the University. These external forces are identified as relating to:

- The alignment of governmental scientific and innovation policies resulting in greater governmental control of research agendas and a focus on the role of research in relation to the economic wealth of the nation.
- Increased competition for funds resulting from: research funding focusing on large, multi-disciplinary projects being required to address 'grand challenges'; concentration of resources on multi-disciplinary world class resource; reduced state funding and need to develop alternative sources of funding.
- Requirements to engage with research users and for research to have demonstrable impact.
- Differentiation and marketisation of universities.

These themes are apparent across all the strategies reviewed, although there is a variable emphasis. This legitimisation tends to be more strongly found at the institutional level, with Department strategies focusing more on issues relating to internal organisation and goals.

Being 'Business-Like'

The review suggested that the use of 'business-like' practices is more strongly articulated at the University than Department strategic level. However, the two areas that come through extremely strongly across all plans was firstly a focus on income generation and, secondly, performance management through evaluation against output measures. This suggests that these aspects of the NM agenda have been strongly internalised by the organisation. Interestingly, there is no apparent demarcation between teaching and research which the literature suggested is increasingly apparent within the sector.

Discussion

The review of selected strategic documents suggests that these research management strategies can largely be characterised by NM in terms of how organisational forms are legitimised and the types of business-like practices being promulgated. NM therefore appears to have had a significant impact at the formal level of the organisation. However, a more in-depth reading of these strategies suggests the articulation of a distinct version of NM. For example, although there is reference to 'increased customer orientation', 'customers' are not conceived here as recipients of a service or product in a 'one-way' relationship. Instead, they are framed as 'stakeholders' with whom the organisation develops strategic and productive relationships. In addition, whilst NM influences within the sector are increasingly pressing for a split between teaching and research, this is not evident here. Indeed, this is neither explicit nor implicit in any of the strategies reviewed. The link between teaching and research appears to be strongly held by the institution and would suggest a more traditional view of the role of HE than that suggested by more managerialist approaches.

Furthermore, it is also interesting to note that there is an emphasis on areas which the literature would suggest are being squeezed out by NM practices. In particular, the Research Strategy aims to ensure collegiality and to support research in the best way for the particular type of research and/or discipline. A commitment is also made to striving to tailor support services to meet academic needs. Similarly, the KT strategy expresses a strong community ethos which is articulated both in terms of relations between all members of the University, and between the organisation and its local and regional communities. Within Department Plans, there is evidence of similar ideas, such as developing research in the most appropriate way for the researcher (Information Systems), or developing a shared sense of research enterprise and recognising the value of each others' work (Sport), or developing and sustaining an enriching work-environment in which creativity and ideas can flourish (Social Sciences).

Thus there appears to be a distinct ideology behind the variant of NM found within the University. Earlier discussions about NM suggested that there were a number of tensions inherent in neo-technocratic NM. These arose from the appropriation of new managerial practices to achieve social as well as economic goals. The same appears to apply here. Neoliberal

logic informs the legitimisation of organisational forms and business-like methods are being used to improve performance. However, this appears to be based around fundamental academic values associated with collegiality and freedom in research. This questions the extent to which these competing values and practices impact upon the individual researcher. This will now be explored through analysis of the primary data.

Individuals' Experiences

Findings and Discussion

Theme / Impact	Research Funding	Outputs & Performance Measures	Academic Freedom & Control	Fragmented Organisation & Mixed Messages	Research Culture
Enabling	Opportunity to enable the development of personal research goals.	Internalising an understanding of research defined by sector and policy metrics.	Relative sense of freedom compared to working on non-university environments.		
	Development of pragmatism - accepting it as integral to the life of a researcher and exploiting funding sources to pursue personal goals.	Developing personal strategies to pursue own research goals in spite of performance measure 'tick boxes'.			
Restricting	Increased pressure on researchers to achieve annual income targets and associated peer recognition and career progression.	Feeling subject to a reductionist view of research. Sense of overemphasis on meeting targets rather than producing high quality research.	Senior researchers feel less in control of their day-to-day activities as a result of increasing management and leadership responsibilities.	Espoused academic related values found at the institutional strategic level do not translate into operational management practices, leading to frustration and disillusionment.	Sense that articulated strategic and institutional position on value of research does not equate with vibrancy of research culture 'on the ground'.
	Challenge to individual sense of academic ideal associated with independent pursuit of knowledge.		Too much freedom arising from absence of effective management leading to frustration and a sense of isolation. Perception that more effective, targeted management practices would enhance research experiences.	Predominating 'business-like' practices had a negative impact on the individual, either because they were poorly implemented, or because they were disassociated from espoused objectives.	Perception of vibrant research culture as critical for the individual researcher, but experiencing a fragmented and patchy research culture in reality.
				Tension for the individual researcher caught between conflicting institutional and departmental level policies.	The gap between the formal and informal organisational culture(s) needs to be bridged.

Figure 2. Summary Findings – The Impact of Management Practices on Individual Researchers

Research Funding

One of the major outcomes of NM on the HE sector has related to reduced funding. Combined with the enlargement of the sector, this has meant increased competition for funds and that universities have had to diversify their income sources. It is clear that Mears has a strong focus on output measurement and sets clear income targets for academic staff. This has had a significant impact on the life of individual researchers. It has become part of their daily life and there is a sense that this leads to pressure on individuals. A Departmental Research Director notes that:

> "20 years ago there was much less pressure on attracting a research income. Research was almost er.. a choice, you could if you wanted to do research then you could, there would be no pressure for all academics to do research.... And now I see whole Universities are seeing research as an income generator as well as a motor of the work. . .so we are all trying to think of how we can diversify ourselves" (Professor [Engineering], p. 12/34-35; p. 13/1-2,9-11).

Indeed, there was a sense of lamenting a time past when HE was seen as being a much more independent world. This was even felt by younger researchers who were not working then:

> "I think probably ten years or so ago it was a lot easier but now it's a lot more competitive." (Senior Lecturer [Engineering], p. 7/9-10).

All interviewees had a strong awareness of the increased competition for research funding which made it not only more difficult to secure funding, but could also impact upon career progression in terms of meeting personal targets and achieving recognition within one's field:

> "That's something I've noticed over the last twenty years, it's so hard now to get funding. It's being quite clever about getting lots and lots and lots of small contributions to your purse . . . But if you want to get noticed, irrespective of whether you are successful, your career will suffer unless you go for the big ones" (Reader [Information Systems], p. 14/2-8).

All participants identified that they had to secure funding for their research and discussed personal income targets. This appeared to be a major preoccupation for all the researchers and in some cases could lead to stress:

> "I mean, I do lose sleep at nights sometime thinking about ummm . . . you know, that I'm not keeping the funding and its worrying about getting the next thing" (Reader [Information Systems], p. 14/20-22).

Furthermore, this can have an indirect effect over what research an individual chooses to undertake. Both Lecturer [Sport] (early career) and Reader [Sport] (mid-career) work in areas in which there is limited external funding. They describe the implications of this:

> "in a way it has been a strategic move, in part, to move into doing the kind of work I am doing now because I can get money, influence policy, blah, blah, blah". (Lecturer [Sport], p. 14/35, p. 15/1-2)

> "more and more you're having to tailor your research to the funding . . . So I am now looking at other types of research that might be less interesting but more likely get the funding". (Reader [Sport], p. 3/11-12)

However, only these two participants suggested that they would change their area of research to secure funding. Instead, the other researchers discussed how they tried to find funding without sacrificing what they wished to achieve (Senior Lecturer [Engineering], p. 8/8-10; Professor [Social Sciences}], p. 6/17-20). For example:

> "But really, what I was doing all the years I was trying to find calls or funding organisations that they, that my research will fit with their priorities rather than trying to change my priorities to fit in a call" (Professor [Engineering], p. 7/7-10).

There was, however, quite a pragmatic sense across all interviews that this is now a 'way of life' for a researcher and is not unique to Mears:

> "funding is frustrating, but is also a reality of doing research" (Professor [Health], p. 4/5)

> "I think it [research funding] has become a little bit worse, but this is not unique for Mears, I mean with the full financial costs, and everybody has got more pressure to bring more money" (Professor [Engineering], p. 7/31-33).

However, this did seem to lead to two major concerns for individuals. The first area of concern was the researchers' sense that the University seemed to want them to obtain money for its own sake. This was associated with a sense that research itself was undervalued and that research success was equated with research income rather than more qualitative considerations. This concern arose from researchers in both STEM and SSH disciplines and at various career stages.

> "Again it comes down to money I think, that's, that's all, the perception is that that is all management is interested in is 'how much do you bring in'?" (Senior Lecturer [Engineering], p. 18/18-19).

> "by the university, it's just you're being judged by how much money you bring in. I don't think it's about the research I think it's just if you're bringing in money . . whether you do that research well or not is neither here nor there" (Lecturer [Sport], p. 12/30-33).

> "I do wonder whether, there is too much emphasis of being seen to get money for the sake of getting money. And that's not unique to Mears by any means, but there is a big difference between getting research grants and being a good researcher (Professor [Social Sciences], p. 8/4-5)

However, it is interesting to note that this was expressed differently by the professor who is a Research Director.

> "I think that the most objective part is by looking at research income. If you accept that the proposals will only be funded if they are of sufficient technical merit or scientific merit then how much income you attract is a good measure". (Professor [Engineering], p. 9/2-4)

This would seem to suggest that the institutional view is one of income being a proxy to demonstrate the quality of the research within the institution. However, if this is the case, that does not appear to be the message that is being received by the researchers, in particular, those who are not operating at more senior, cross institutional level.

The second major concern was the sense that the funding environment was making research more 'corporate'.

> "that can be very frustrating because it is, it is a shift away from the traditional academic way of doing things where it's your research that drives you . . . which does take us closer to a kind of corporate world of, of research" (Professor [Social Science], p. 6/34-35, p. 7/1-3)

One Senior Lecturer was a mid-career researcher who had been successful in securing several small grants and, more recently, two substantial Research Council grants. However, the real impact of this sense of 'corporatisation' appeared to be personal, challenging his sense of himself as a researcher:

> "it just sort of taints that for me because I have this, sort of, scientific idealism in my head that I kind of think if it's a good idea and it's pushing the boundaries, then it should go forward and it shouldn't be dependent on how much money is available (I3, p. 7/9-12). "As I said to you, it's almost prostituting yourself to get money" (Senior Lecturer [Engineering], p. 7/25-26)

In spite of this challenge to his idealistic views of how research 'should be', he appears to remain pragmatic about the current reality of research work:

> "But that's what I came here for and I knew that was part of it. It just makes you feel a bit more like a consultant than I'd like, really (Senior Lecturer [Engineering], p. 7/26-28).

Not all experiences of research funding, however, were negative. Some researchers did express enjoyment in the funding process itself and the opportunities funding created for them. This related to a love of the creative process of writing research proposals (Lecturer [Sport], p. 3/22-24; Lecturer [Social Sciences], p. 4/14-15) and also the resulting participation in research projects (Professor [Engineering], p. 7/10-12). This latter point is particularly illustrated here:

> *"That's a funded project?* Yes, and it's a great consortium. Yes, it's going back to this commitment to work. We're already writing [Project Name] and the call hasn't even come out yet. WOW! Getting a consortium like that . . . I'm incredibly lucky to get involved" (Reader [Information Systems], p. 5/35 – p. 6/1-2).

Funding thus has a major impact on the individual. It challenges their sense of what it means to be a researcher and the academic ideal associated with the independent pursuit of new knowledge. It can lead to pressures associated with annual income targets and peer recognition and, consequently, career progression. However, it can enable them to pursue their own projects and some researchers do enjoy the process of securing funding and the opportunities it can create. In addition, there is a sense of pragmatism – funding is recognised as being part

of the life of a researcher and individuals actively seek ways to use the system to pursue their own research projects and advance their own careers.

Outputs and Performance Measures

In addition to funding targets, all interviewees talked about having annual targets set by the University as part of its line management system. There is a shared understanding of what constitutes a measure of 'successful' research activity within the sector which individuals appear to have internalised. As one mid-career researcher puts it:

> "because strategy is publish, complete PhD students and bring money in. No matter how you want to post it, that is what it is. And I know that, and I know that internally, so I just need to get on and do that. I mean that is what a research active institution should be doing" (Reader [Sport], p. 11/1-4).

However, there is a concern that attempts to measure research outputs have lead to a fundamental shift in how research is treated and that it is now viewed as:

> "something that can be quantified reduced to outputs, products, cash raised, numbers of students supervised, and I think that is, as an approach, is quite pervasive now, and I think that has, that may well have gone too far (Professor [Social Sciences], p. 16/27-30).

In spite of this, individual researchers did not necessarily equate such performance indicators with high quality research and these targets would not necessarily drive what research they decided to do:

> "So we could very consciously focus on the development of what we consider to be good research and not focus on how we tick the indicator" (Professor [Health], p. 17/1-3).

Even more than that, however, individuals consciously engage in strategies which enable them to achieve required outputs and, consequently, give them the freedom to pursue their own research agendas (Reader [Information Sytems], p. 13/21-25; Reader [Sport], p. 11/16-17). This sense of working to achieve one's own research goals in spite of output requirements extends to the Research Assessment Exercise (RAE). There is considerable discussion within the sector about the RAE and it had been expected that this would be a key factor in relation to individuals' experiences. Whilst it was widely recognised that the RAE had played a significant role in affecting the UK research culture and the sector within which they worked, individuals did not talk very much about it impacting directly upon their working lives. Where direct impact was identified, this related to how they used their research outputs rather than directing the nature of their research (Professor [Engineering], p. 17/10-11).

Indeed, few researchers appeared to be aware of, or concerned about, the detail of the proposed changes to the RAE, with the development of the Research Excellence Framework (REF). Most seemed to be quite phlegmatic about it (Reader [Information Systems], p. 9/14-16):

> "So I suppose from that point of view you do start thinking about where you're going to target, your publications and stuff. But umm… no, I mean my view on that kind of thing

> is to just sort of get your head down and get on with it. They will probably have changed the goal posts again anyway before we get there, because they just seem to be constantly doing that" (Senior Lecturer [Engineering], p. 21/10-14).

The main exception to this was the Research Director who expressed concern about the potential for increased game playing around the use of citations. However, even he notes that this is the standard measure from which, like it or not, we cannot escape:

> "so there is game playing and we should be careful of this system and, of course, no system is foolproof" (Professor [Engineering], p. 9/29-30).

Clearly, outputs and performance measurement are also part of the daily life of a researcher. Researchers are very aware of what outputs they need to produce in order to be successful in their career. However, whilst this seems to shape the world and research culture around them, researchers do not appear to be driven by these outputs. They engage in strategies which enable them to tick the relevant assessment boxes, whilst pursuing their own research goals.

Academic Freedom and Control

The literature suggests that one of the main ways in which NM is impacting upon universities is limiting academic freedom and the extent to which academics can control their own work. Freedom here is understood as academic freedom, namely that a researcher is free to pursue their own lines of enquiry. Alongside this, however, is the idea of control which was associated by participants with the ability to decide what they do on a daily basis. These two notions are distinct but appear to be closely linked within the individual's experience.

The assessment of Mears' research related strategies suggests that the university still values academic freedom and seeks to provide an environment in which this can flourish. For many of the participants the main factor that originally attracted them to research in academia was associated with intellectual challenge and creativity, and the freedom to pursue their own areas of research interest. This might relate to a satisfaction in personally learning new things (Professor [Health], p. 3/20-23; Senior Lecturer [Engineering], p. 5/14-15), the "thrill of the chase, starting out on something and not quite knowing where you are going to end up" (Professor [Social Sciences], p. 5/23-24), the challenge of staying at the forefront of one's field (Lecturer [Social Sciences], p. 4/23-31), or because a scientific career is less boring than a business career (Professor [Engineering], p. 1/13-18; I10, p. 2/5-19). Indeed, most had spent time working in private sector organisations before joining the university. One early career researcher had been working for a private research agency but wanted to come back to the academic world because she missed the creative thinking and control over her work. She seemed to be much happier as an academic and felt that now: "basically I can do whatever I want" (Lecturer [Sport], p. 14/21-22). Similarly, another early career researcher had been working in industry for several years and was drawn back to academia because:

> "I just preferred the intellectual freedom . . .the stuff with industry . . I just sort of found too much of the time my hands were tied" (Lecturer [Sport], p. 2/8-11).

Another early career researcher notes:

> "I could do anything. I really research for ever what I really want to do. And I think that really, it doesn't happen often in many jobs that you can really do what you want to do (Lecturer [Social Sciences, p. 4/16-18).

It would be reasonable to assume that all individuals are constrained to a degree by their work environment in terms of what they can or cannot do, and how. Indeed, it could be questioned how far there can ever be 'absolute' freedom given the range of interests and actors which make up a 'work community'. In this case, participants seem to feel they have more freedom and control working within the university than in other organisations. Thus there is a sense of relative freedom.

In terms of their daily working life, most participants felt that they did have control over what they did:

> "I also like the academic, the freedom that an academic environment gives you. Other than my teaching, I come in and what I do on a daily basis is up to me" (Reader [Sport], p. 2/33-34).

> "Yes, I am in control, yes, yes, yes. . . . I mean, it is left up to me to pursue the best avenue to support my research (Professor [Engineering], p. 14/12-17).

This appeared to some degree across all career stages and discipline types. Where the sense of control seemed to lessen was for those in more senior positions, or for those individuals who did not seem to actively engage in self-management. One professor felt that she did not have control over her work: "Do I have the control? I don't now because I just don't have the time" (Professor [Health], p. 8/23). In spite of this, however, she still had the freedom to pursue her own lines of research: "nobody dictates what I do my research in. . . I don't feel that I have any obligation, any sense of obligation to go one way or another" (Professor [Health], p. 9/8-9).

The Research Director suggested that he currently had little time for research as much of his time was taken up with administrative tasks "and sometimes it's the number of meetings I have to go to which is the worst part" (Professor [Engineering], p. 2/30-31). However, there was not a sense that this was a new phenomenon, it was seen as 'part of the job' as one becomes more senior (Professor [Engineering], p. 12/18-20).

It was interesting that some interviewees expressed their level of freedom in a negative way in that they felt their freedom in part arose from poor management practices.

> "but certainly, in my Department we get away with blue murder. Umm . . . which is great because you can, it gives you an enormous amount of freedom, but it is also pathetic because it means things aren't co-ordinated and they're not coherent (Professor [Health], p. 13/21-23).

> "setting me targets around papers is highly irrelevant because that, that will just happen . . . whereas I could have been set some quite interesting targets" (Reader [Sport], p. 12/7-10).

There is a sense of frustration that although such management practices can result in increased freedom and control for the individual, more appropriate or effective practices might actually enhance their research experience by providing a better research environment. In addition, some of the researchers who expressed a high level of freedom and control link this to a sense of isolation within the University.

> "Yeah, on a personal level definitely and I've created my own niche and my own networks and my research areas. I don't feel I fit into a bigger picture in Mears" (Lecturer [Social Sciences] p. 14/34-35).

> "Nope, I do my appraisals once a year otherwise I have nothing to do with [Head of Department] at all, I'm invisible" (Professor [Health], p. 16/16-17).

> "Department wise, I don't feel there is any support at all"; "I feel I swim very much on my own here". (Lecturer [Social Sciences], p. 11/7-8).

This tended to be expressed as more of an issue in three Departments where the research culture appears to be less well developed. This is discussed further in paragraph 2.5 below.

For all participants, there was a strong sense of retaining academic freedom in their work and they did not feel overly constrained by either the institution or requirements such as research funding. Whilst research funding could limit positive freedom (being able to do exactly what one wants), all interviewees expressed a sense that they had more freedom and control than they would have working elsewhere. Issues of control seemed to depend on the individual's capacity for self-management and career stage. Within three Departments, there was a sense that better management practices would actually support the research activity and enhance the individual research experience.

Fragmented Organisation and Mixed Messages

Throughout all accounts, the University appeared to be experienced as a fragmented organisation. Participants' views and experiences tended to be extremely localised to their own Department. No participants actually felt able to comment meaningfully on the University as a whole, although they had very strong views about their own Department. For example:

> "It's fragmented I think. I think there's lots of people doing good research in pockets. . . my comment around it being fragmented, I'm not sure whether that's a true reflection of the institution or a greater reflection of the Department. It's certainly true within the Department . . Actually, I'm not that aware of the research culture of the University" (Reader [Sport], p. 8/18-27).

Interestingly, many interviewees had quite positive views of the University which contrasted with their negative views of their own Department. This early career researcher's view of her Department, compared with her view of the University, is an interesting example:

> "[the Department] seems quite bitchy, and back stabbing and that has an impact upon your job and how motivated you are for your job and whether you want to work with

> colleagues or whether you want to stay at home and work" (Lecturer [Sport], p. 10/31-32).
>
> "So you know, Mears, I'm quite, you know, happy being here, because you know it does give me the scope, and they want you to be doing the research" (Lecturer [Sport], p. 11/26-28).

It is perhaps not surprising that alongside this organisational fragmentation, there was a strong sense of 'mixed messages'. For example, in the case of this young researcher who has been successful in meeting research targets:

> "it's kind of ironic . . .I've done well on the research front, which the University has been pushing, but still they won't give me a permanent contract, so there's . . . you kind of get mixed messages. (Lecturer [Sport], p. 34/11-12).

Indeed, this inconsistency of message appears to be quite structural and was expressed by all interviewees, for example:

> "But I've become more aware of, sort of, competing pressures at various levels of management want you to do research and various levels of management want you to do teaching. . . .I suppose my perception of it is, it's very much the, the higher levels of management that are sort of pro research and it seems to be just a bit of a Chinese wall somewhere that it doesn't filter down necessarily to this kind of level" (Senior Lecturer [Engineering], p. 14/29-32).

Analysis of strategic documents has demonstrated a strong formal organisational identity and focus in relation to research. However, this focus appears to be lost when it is mixed with the other day-to-day activities within the Departments. For example, one mid-career researcher felt that a particular challenge relates to creating a vibrant research environment. Whilst he felt that this would be understood "higher up in the University", "in this Department I think there is a lack of understanding of what it takes to create that environment" (Reader [Sport], p. 5/33-35).

The only exception to this was the Research Director who appeared to have a sense and experience of the University as a whole. For the rest, who did not operate at the institutional level, the impact of this institutional fragmentation and mixed messages appeared to be significant. It seems to create a tension for the individual who is caught in between conflicting University and Department priorities. Moreover, there was a sense of frustration and disillusionment since achievement on the research side did not seem to be valued within Departments, and it was felt that more effective management practices would better support the individual and collective research activity.

Research Culture

For individuals, the experience of the fragmented university aligns closely to issues relating to the research culture. Through its strategies, the university presents itself as being research intensive with a strong message regarding the role and value of research to the institution.

However, at the level of the individual, it is not clear that this necessarily equates with having a vibrant research culture. For all participants, the research culture was identified as critical to being able to undertake good research.

> "if you're not part of the vibrant community of researchers I think that you can't do good research. Umm..., it absolutely has to come down to the institution" (Professor [Health], p. 21/3-5)

Interestingly, the concept was distinguished from widely accepted indicators of 'culture':

> "And if somebody is actually producing publications, hopefully supervising good students who complete and getting in the research grants and that's taken as being research culture, and I don't think that is research culture, I think it's only part of it" (Professor [Social Sciences] 13/9-11).

Instead, individuals associated the idea of research culture with having a shared research identity on the website (Professor [Health] 9/2-9), or being able to openly share and discuss ideas without fear (Reader [Sport] 9/11-13); feeling supported and valued as well as constructively supporting others' grant proposals (Lecturer [Sport] 7/1-2, 13/24-25). This appeared to relate to an underpinning value of collegiality.

There was some sense that there had been an improvement in the University's research culture following moves to develop the University's research status. However, there did not seem to be a sense among any participants that they were working in what they would consider to be a 'research intensive' institution. Most interviewees felt that the research culture was patchy and 'fragmented' (Reader [Sport], p. 8/19) with 'pockets of excellence' (Professor [Health], p. 13/14) and they were unsure whether the description of the university being 'research intensive' was an accurate one (Senior Lecturer [Engineering], p. 12/28-35). This successful mid-career researcher (Senior Lecturer [Engineering] was based in a large successful Department with the strongest research track record and culture within the institution:

> *"So what do you understand by research intensive then?* Yeah, I, I think, my understanding from the VC's message is that we have arrived and we are a research based institution. Again, I don't have all the facts but I don't think, to my mind, that that is an accurate picture . . . there is not the, the infrastructure or the staffing to support that" (12/26-35).

His experience suggests there is a gulf between the University's stated policies and individuals' perceptions and experiences. As noted by one of the Professors, the existence of strategy does not necessarily result its effective implementation:

> "but I think, as with many such strategies [referring to the Research Strategy], there was a gap between the strategy and the implementation and I think that gap is, is sometimes quite large" (Professor [Social Science], p. 13/27-29).

In some areas, this gap between strategies and practice appears to have had a significant, and largely negative, impact. Notably, 9 out of the 10 participants struggled to express a sense of

the culture of the University. Instead, their experience of the University was very much based on their experience within their Department where, in the main, a strong research culture was felt to be lacking. For example:

> "my comment around it being fragmented I'm not sure whether that's a true reflection of the Institution or a greater reflection of the Department. It's certainly true within the Department. Umm.. Actually, I'm not that aware of the research culture of the University so my comments are probably more, more closely aligned to the Department. The Department's research culture is very, very fragmented there is a lack of understanding between key members of the management. (Reader [Sport] 8/15-29).

> "But, I think there is a bit more a departmental culture there [where interviewee used to work] and I think that is really important because it's the sense of being part of a department that fosters a research culture. Umm.. And we don't really have that here, I've tried very hard here to create it and I think things are better than they were, but that's still limited" (Professor [Social Sciences 13/1-11].

> "I know it's our fault and I'm not blaming the Department but everybody just comes in and does their two days usually just goes home and nobody invests in [Mears] from my, into the research culture of [Mears]"; "And I've learnt, one bad thing I've learnt in my five years here, is to basically protect my time more and more and not to volunteer for things. ."; "And basically what I've done is I've outsourced my networks and research cultures" (Lecturer [Social Sciences] 10/1-2; 10/1-17; 11/14-16).

The main exception to this arose from the Engineering Department, where there was a general sense of a more positive and supportive research culture. This is, perhaps, not surprising given its more established track record of undertaking research:

> "I mean Engineering was one of the few areas that they were carrying out research before the final initiatives. So this is something that has, as I would say, it was always strong within Engineering, so it has not changed really" (Professor [Engineering] 12/13-16).

In addition, the nature of the research being undertaken means that researchers are more used to working in teams and securing research funding and are therefore better able to implement these types of university strategies. Furthermore, the Research Director for that Department, who plays a role at the institutional level, felt there were many positive initiatives that supported the development of collaborative working between colleagues through mechanisms such as research centres and networks, internally peer review for grant proposals and mentoring for early career researchers (Professor [Engineering] 8/15-31; 4/30-35).

The absence of what individuals felt to be a strong research culture had a significant impact on their working experience. Experiences were variable across the Departments, but at that time were largely felt to be negative and adversely impacted individuals' sense of community within the institution, their levels of motivation and their perception of support for their research activity. Furthermore, the gap between the values and objectives advocated in University strategies, and those experienced operationally, caused frustration and, in some cases, disillusionment.

Conclusion

This project further developed understanding of the nature of New Managerialism (NM) within Higher Education (HE) and what this means for individual academics doing research work. Discussion of the impact of NM on HE provided a framework which was used to consider a single University. It was found that at the formal level the University displayed a hybridized version of NM. The legitimisation of organisational forms and use of business-like practices were being appropriated to support core research related values associated with collegiality, academic freedom in research and the symbiotic link between teaching and research.

Key themes impacting upon the individual experience were identified as:

- research funding;
- performance measurement;
- academic freedom and control;
- fragmented organisation and mixed messages;
- research culture.

It was evident that individuals were aware of the nature of management practices and how these affected their research environment. However, all interviewees spoke about their research with commitment and enthusiasm, and informally valued the relative freedom they experienced within the University to direct their own research activity. The impacts of identified management practices on the individual researcher were classified as being either enabling or restrictive. They were enabling, however, only in the sense that individuals could negotiate their engagement with university systems in order to pursue and achieve their own research goals. Researchers could achieve their goals in spite of management practices, rather than because of them. This is distinct from the notion of enabling as actively empowering or facilitating researchers in their work. However, it does suggest how researchers continue to pursue their research with apparent enthusiasm and success (a result of enabling impacts), in spite of negative views on, or experiences of, particular management practices (a result of restrictive impacts). Indeed, the restrictive impacts had a notable, and primarily negative impact on individuals' research experience. They could feel isolated, under pressure, undervalued in relation to other imperatives, subjected to an overemphasis on meeting targets rather than trying to produce high quality research.

Furthermore, the findings support earlier studies by suggesting that the management environment for HE can be characterised by New Managerial ideologies and management practices (Davies et al, 2006; Deem et al, 2000; Shelley, 2005; Henkel, 2000). However, it does extend the understanding of how NM has been translated within HE by exploring the particular hybrid nature of NM at Mears University. In addition, the experiences of Mears' researchers corroborate studies suggesting that individual academics continue to maintain their own academic value system and engage in strategies that enable them to pursue their own agendas within current managerial regimes (Archer, 2008; Clegg, 2008; Bennich-Bjorkman, 2007). Moreover, the findings suggest that academics now accept many of the practices associated with NM as part of the daily life of being a researcher, thus supporting the

assertion that making a stark distinction between current NM related practices and previous more academic based practices may no longer be relevant (Kolsaker, 2008). In conclusion, NM is now an integral part of the HE environment and not a separate influence distinct from academic management.

However, undertaking a targeted case study provided an interesting opportunity to consider what hybrid NM practices meant for this university and its researchers. Experiences at Mears University suggested that there was a strategic implementation gap. It had been expected that this would mean that NM practices apparent at the strategic level would not filter down to the individual experience and therefore have limited impact. However, what this meant in practice was that the softer academic values found at the institutional strategic level did not appear to be translated into day-to-day management practices. Interestingly, this meant that harder 'business-like' practices seemed to have more of a negative impact on the individual, either because they were poorly implemented, or because they were disassociated from the core values they were intended to support. Researchers appeared to feel that they were successful in their research in spite of management practices at the Department level, rather than because of them. Indeed, this supports recent suggestions that the success of research strategy implementation will be determined in part by the extent to which 'espoused' values (what an organisation says it will achieve) matches the 'objectives-in-use' (what an organisation is perceived to be seeking) (Bilot & Codling, 2011, p. 106). In this instance, a mis-match was highly detrimental to researchers' motivation and sense of commitment to the University.

In addition, it could be speculated whether management practices based on NM are necessarily the most appropriate tools with which to organise research activity. Individuals' discussion about the motivations for, and process of, doing research strongly suggests that this type of work does not fit the neo-Taylorist assumptions upon which NM is based. It can be questioned to what extent such practices take into account the particular nature of 'doing research', and whether they effectively harvest the motivation, creativity and ability of academic staff to deliver research activity (Billot & Codling 2011). As both Government and universities increasingly try to manage and control research activity, it may be timely to consider the nature of research work in more depth in order to identify the most effective management techniques.

Methodologically, it was proposed that the findings of earlier studies had been informed by their particular approach. This related to the extent to which they pursued a realist or interpretative method. It was suggested that this may have been one reason why studies resulted in differing conclusions regarding the extent to which NM management practices had positive or negative effects. Although the main thrust of this study was interpretative, situating individual experiences within their organisational context was an attempt to recognise that individual meaning-making takes place within particular frameworks to which individuals respond. Using a case study method to explore this proved to be appropriate, demonstrated by the thick and rich data gathered from which clear conclusions could be drawn. In addition, it made it possible to identify that individual perceptions at the informal level varied significantly from the formal view. Reviewing strategic level documents (formal) and the individual experience (informal) was intended to address this. The experience at the informal level was

informed not only by management practices, but also by personal values and beliefs, relations and networks, power structures, individual motivators, perceptions and norms. Such factors were shown to influence the interaction between individuals and management practices and consequently, the impact of the latter. Although this is beyond the scope of this project, more in-depth investigation around this could lead to further insight into how researchers make sense of their role and work environment and, from a management perspective, how best to motivate and support research work.

Next Steps – Developing Practice

It is recognised that in order to effectively facilitate and support research work, it is necessary to understand the effects changing practices, values and norms have on the individual (Robinson, 2009, p. 109; Wimsatt, Trice & Langley, 2009, p.71). This is both a challenge and an opportunity for research managers. This particular case study enhanced our understanding of how particular management practices, and their associated values, were impacting individuals. It was consequently possible to develop practices to proactively enable researchers, whilst minimising restrictive impacts of wider university practices. This included measures such as:

1. Enhancing research cultures by building new research communities and reinforcing institutional level values through:
    - The development of thematic interest groups to build enabling environments that foster productive research cultures, the development of new collaborations and preparations for future funding calls.
    - Foregrounding strategic level values by celebrating and raising the internal profile of research successes.
2. Tailoring support measures to meet researchers' needs:
    - Offering a bespoke Grant Academy Programme to less experienced researchers to develop research funding skills and confidence, receive mentoring and establish internal research networks.
    - Developing a masterclass workshop series to provide flexible support to academics, tailored to their articulated needs.
3. Supporting academic freedom and control:
    - Building opportunities for academic research leadership by establishing a Strategy Group that cuts across operational management structures to drive and co-ordinate targeted research development activities.
    - Working one-to-one with researchers to help them navigate operational management structures and processes to achieve their research goals.

By delivering such activities, the Research Office can try to close the strategic implementation gap. The next challenge is to embed such measures and values more widely within the University in the context of its multiple and complex agendas.

Author's Note

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Appendix

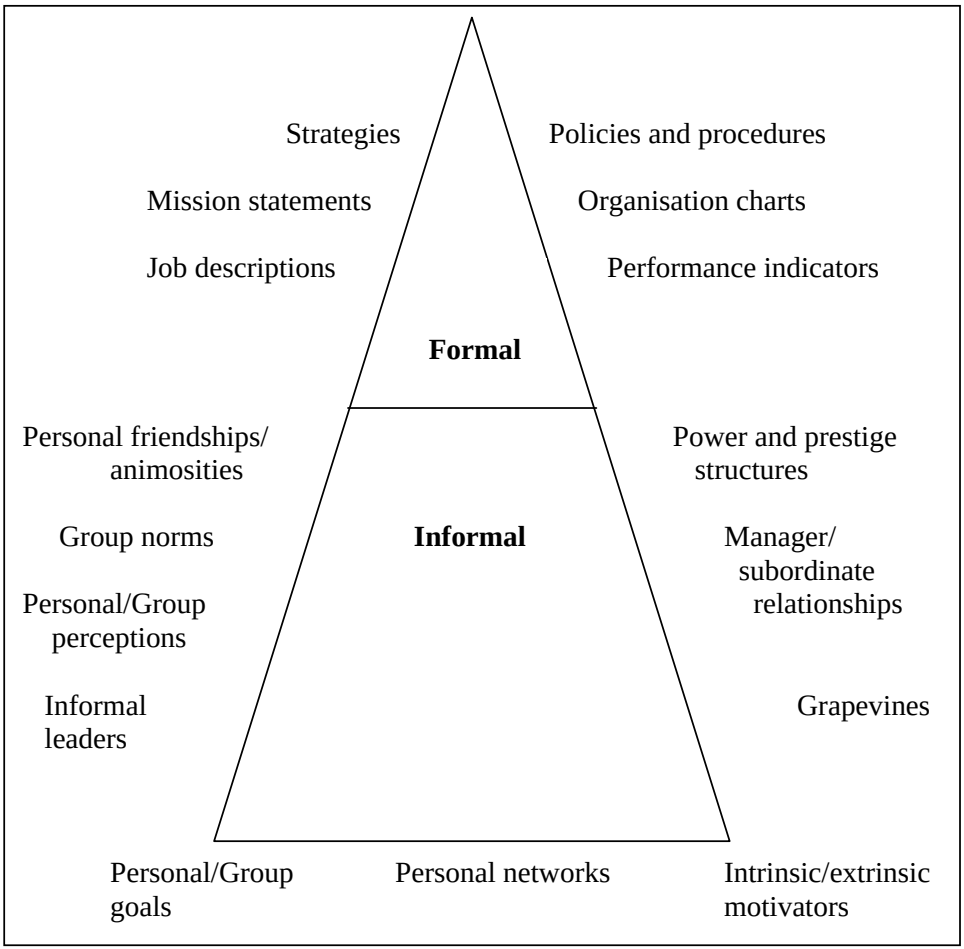

Figure 3. Formal and Information Organisation
(Adapted from K. Lysons 1997 cited in Mullins, 2002, p.99)

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The Resource Allocation Program at the University of California, San Francisco: Getting More from Intramural Funding Bucks

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Abstract: *Intramural funding programs within both large and small research institutions are an essential mechanism to foster collaborative, novel, or preliminary research activity, and to further institutional research strategic goals. At most research institutions in the United States, these funding opportunities are managed by each funding agency or program, independently of each other. The lack of a shared administrative structure for these independent programs can lead to inefficiency and ineffectiveness of any one program. For example, a researcher must navigate several websites to determine which funding opportunities are available and then face multiple submission deadlines scattered across the entire academic year. The Resource Allocation Program (RAP), a shared*

administrative structure at the University of California, San Francisco (UCSF), has centralized the announcement, submission and review process for opportunities offered by multiple intramural funding sources. Results of the shared structure include increased efficiency due to consolidation of internal review committees, increased visibility of funding opportunities, increased transparency and consistency of the selection process, and enhanced availability of valuable review feedback.

Keywords: *intramural funding, seed funding, scientific review*

Introduction

Intramural funding programs within both large and small research institutions are an essential mechanism to foster collaborative, novel, and preliminary research activity, as well as further institutional research strategic goals. Seed or pilot funding has been critical to individual research efforts, enabling researchers to establish experimental feasibility and generate preliminary data for more mature grant submission efforts. As Balaji and colleagues noted in their study, receipt of internal awards of even $20,000 can serve to jumpstart research projects and their subsequent higher-level funding (Balaji, Knisely, and Blazyk, 2007). Research institutions and their associated individual programs and departments can utilize such internal funding mechanisms to strategically support specific areas of research. The University of California, San Francisco (UCSF), like many large research institutions, has many internal funding programs sponsored by private foundations, large National Institutes of Health (NIH) funding-based centers, departments, and schools.

At most research institutions, intramural funding opportunities are run independently of each other. In 2007, UCSF developed an intramural funding opportunity management program that accommodates multiple funding agencies/programs and grant mechanisms, simultaneously offering much added value to the campus-wide intramural funding enterprise. Having determined that good models for efficient intramural funding opportunity management did not exist at similar institutions, the UCSF Clinical and Translational Science Institute (CTSI) proposed, through funding from its NIH CTSA grant (PI-Dr. Joseph McCune), to establish the Strategic Opportunities Support (SOS) Center that would support a seed grant funding program. The SOS Center developed an initial infrastructure for this seed funding program that allowed for efficient publicity, application and review of seed funding proposals. We soon realized this infrastructure could be utilized more broadly across the campus.

In an effort to support the most promising novel research ideas and young investigators, as well as the work of established investigators and internationally recognized faculty, the SOS Center further improved its initial infrastructure for the distribution of seed funds. The new, improved infrastructure, based in part on the NIH's Center for Scientific Review (CSR), was named the Resource Allocation Program (RAP) and was launched in the fall of 2007. In 2011, RAP was placed under the centralized management of the Executive Vice Chancellor and Provost's Office in order to realize the objective of supporting the entire campus and additional funding programs. The SOS Center continues its mission within CTSI and participates in the RAP consortium.

RAP is a campus-wide program responsible for coordinating intramural research funding opportunities. RAP serves as a consortium composed of numerous (currently 16; see Figure 1) UCSF funding agencies that may share overlapping goals while maintaining full autonomy over their funding mechanisms and awardees. (At UCSF, major funding programs are often referred to as "funding agencies".) This cooperative venture between RAP and UCSF funding agencies awards nearly $5 million per year to UCSF faculty and distributed 145 awards during FY 2012-2013. RAP is designed to harmonize the award process by providing a standardized, centralized, and transparent process for the submission, review, and tracking of intramural research funding. This single-application process allows for a more efficient and cost-effective approach.

Prior to the 2007 establishment of RAP, each UCSF funding agency ran independent competitions. A researcher had to navigate several websites to find out what funding opportunities were available and then face multiple deadlines, scattered across the entire academic year, in order to submit applications via primarily a "paper" or manual submission process. The review process was anything but uniform as each agency handled the review differently and reviewers were recruited on an as-needed basis. The reviewer pools utilized by each agency were fairly small and not able to offer broad skill sets. Conflicts of interest within each agency were a constant challenge during both the review and award process.

Program Description

RAP is a central institutional resource at UCSF, administered by the Executive Vice Chancellor and Provost's Office and its component Research Development Office (RDO). Specific objectives of the program are to:

- publicize intramural funding opportunities of member agencies and coordinate high-quality review of proposals by experts appropriate to the proposal topic;
- coordinate funding of proposals among the funding agencies, maintain a database of prior proposals, and publicize successful applications on the Internet;
- provide a forum for inter-agency communication regarding any aspect of the application process; and
- carry out self-evaluation by developing metrics for success according to the RAP objectives.

RAP's benefits are well explained in its slogan, "One Application, Many Funding Opportunities, One Deadline." Llorens and Kellough (2007) described the increased efficiency and performance of a "one-stop" recruitment process in their discussion of centralizing personnel administrative services. For similar reasons, RAP was transitioned centrally on campus in order to increase the overall efficiency of intramural funding processes; to increase the visibility, accessibility and ease of use for researchers; and to minimize the administrative redundancies of the application process among funding agencies. RAP provides a common application process and a common deadline for a wide range of intramural grant mechanisms. Funding opportunities are open to all UCSF appointees in all UCSF schools and affiliated sites.

Since its inception in 2007, RAP has grown from managing three intramural funding programs to the current 16 programs, whose funds come from a variety of intramural and extramural sources. RAP's founding members comprised the UCSF School of Medicine Research Evaluation and Allocation Committee, the UCSF Gladstone Institute of Virology & Immunology Center for AIDS Research, and the CTSI SOS Center. UCSF's Academic Senate and the Helen Diller Family Comprehensive Cancer Center joined RAP at a later date. As additional funding agencies have joined RAP, the number of grant mechanisms has increased in number and diversity, as shown in Figure 1 below.

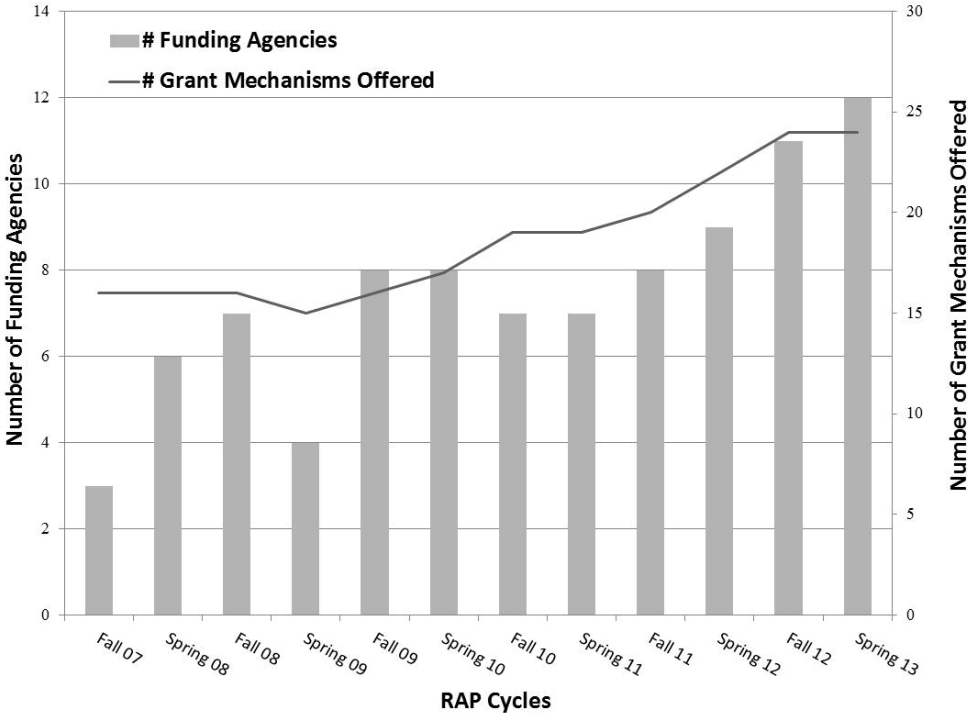


Figure 1. RAP Growth from Fall 2007 to Spring 2013. This figure includes only those agencies that use the full spectrum of RAP services: funding opportunity dissemination, submission and review management. Some intramural funding agencies choose to use only the dissemination and submission capabilities of RAP.

Organizational Structure and Governance

Bill Kirby, a long-time expert in research administration, described the need for programmatic commitment to quality, strong customer and stakeholder focus, and built-in continuous improvement processes in his Quality Management Model for successful research administration programs (Kirby, 1992). He went on to describe in a later paper the need to understand

research administration programs as "systems" or consortia of "interdependent components" or stakeholders (Kirby, 1996). The RAP founding leadership also recognized the value of group buy-in and stakeholder cooperation in order to establish a successful program structure. Thus, RAP has a multi-dimensional leadership structure that includes several entities, all playing a significant role in the program's governance.

The operational RAP leadership team includes the chair and vice-chair of the RAP Executive Committee, the RAP Program Manager, and the Research Development Office Director. As shown in Figure 2, the multi-dimensional leadership team is guided by two committees: an Executive Committee and a larger RAP Committee.

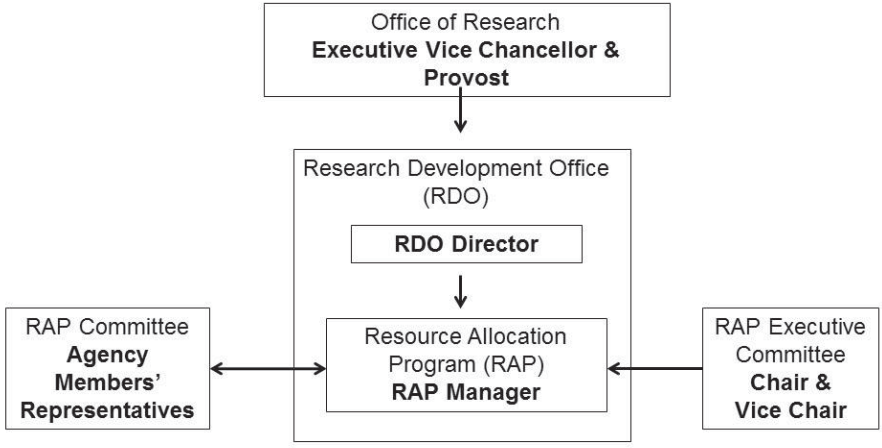


Figure 2. RAP Organizational Structure

The Executive Committee is composed of a chair, vice-chair, and program directors (all of whom are faculty members) whose programs have funded more than 10 percent of RAP awards in the previous two cycles. The Executive Committee provides guidance on program policy and operational issues, and meets on an as-needed basis. The committee's chair and vice-chair are appointed by the UCSF Executive Vice Chancellor. The term of office for both is three years and is renewable.

The RAP Committee, an essential aspect of the consortium-nature of the program, is composed of faculty directors and staff of the participating funding programs. Each funding program appoints one faculty member to the committee, as well as one staff member, usually a program manager, to improve up and down communication and increase effectiveness. Although faculty opinion is essential, we recognize that in order to achieve successful implementation, it is also important to involve staff members at the early stage of any discussion. Just as a scientist brings valuable perspective on medical and scientific issues, administrators can weigh in on the feasibility of programmatic matters such as budgeting, project timelines, and resource availability.

The RAP Committee regularly holds a monthly teleconference that allows all members to participate in continuous program improvement. RAP leadership requires consulting with the entire committee on significant changes regarding policy or major program improvements. This committee convenes in-person twice a year to make final funding decisions at the end of each cycle, and annually for a programmatic retreat.

RAP Program Features

Leslie Wimsatt and colleagues presented the highlights from a faculty workload survey conducted by the Faculty Standing Committee of the Federal Demonstration Partnership in Washington, D.C. (Wimsatt, Trice, and Langley, 2009). This 2009 survey highlighted the heavy administrative burden that is placed on our research faculty, with upwards of one-third of their time spent on pre- and post-award activities. Add to this the fact that grant funding success rates at NIH, the largest funder of research grants in the US, has declined by nearly 30% since 1996, sitting at approximately 18% for R01 equivalent awards (Garrison & Drehman, 2013), and we have a highly competitive funding environment and a limited amount of time available for researchers to spend on administrative tasks. For these reasons, among others, RAP has sought to optimize the ease-of-use to research applicants and maximize the potential funding success rate for any submitted proposal through a multi-faceted approach described in further detail below.

Established Funding Cycles

RAP offers two funding cycles per year: spring and fall. A typical cycle timeline is shown in Table 1. Discrete, regular cycles are valuable to researchers and research administration staff who are involved with the process. Researchers are better able to plan their grant preparation responsibilities. In addition, this biennial cycle supports good planning and efficient time and resource management by administrators within both the RAP program and the funding agencies.

Table 1. Typical Cycle Timeline

Spring 2013 Cycle Timeline	
Date	**Task**
Mon January 7	Provide Website/RFA changes
Mon January 28	Request for Applications
Mon February 25	Application Deadline
Mon March 4	List of applications is sent to RAP Executive Committee
Fri March 8	RAP EC assigns applications to Review Committees
Thu March 14	Applications are distributed to the chairs/support staff
Thu March 21	Review Committee chairs assign applications to reviewers
April 29-May 7	Review Committee meetings take place
Mon May 13	Scores are compiled and distributed to funding agencies
May 17-May 24	Funding agencies decide funding priorities
May 28-June 5	"Horse-Trading" Session to make final funding decisions

Comprehensive Marketing Strategy

The launch of each cycle is supported by a multi-pronged marketing plan aimed at making the campus research community aware of available internal funding opportunities. RAP broadcasts the launch of each funding cycle broadly, highlighting changes such as the addition of new funding agencies or programs or the addition of new grant mechanisms. For each cycle, an email from campus research leadership on behalf of RAP is sent to faculty and researchers, a web article is published on the UCSF website, competition information is posted on the RAP website, and posters and flyers are distributed around campus. A sample poster publicizing the spring 2013 cycle is shown in Figure 3 below.

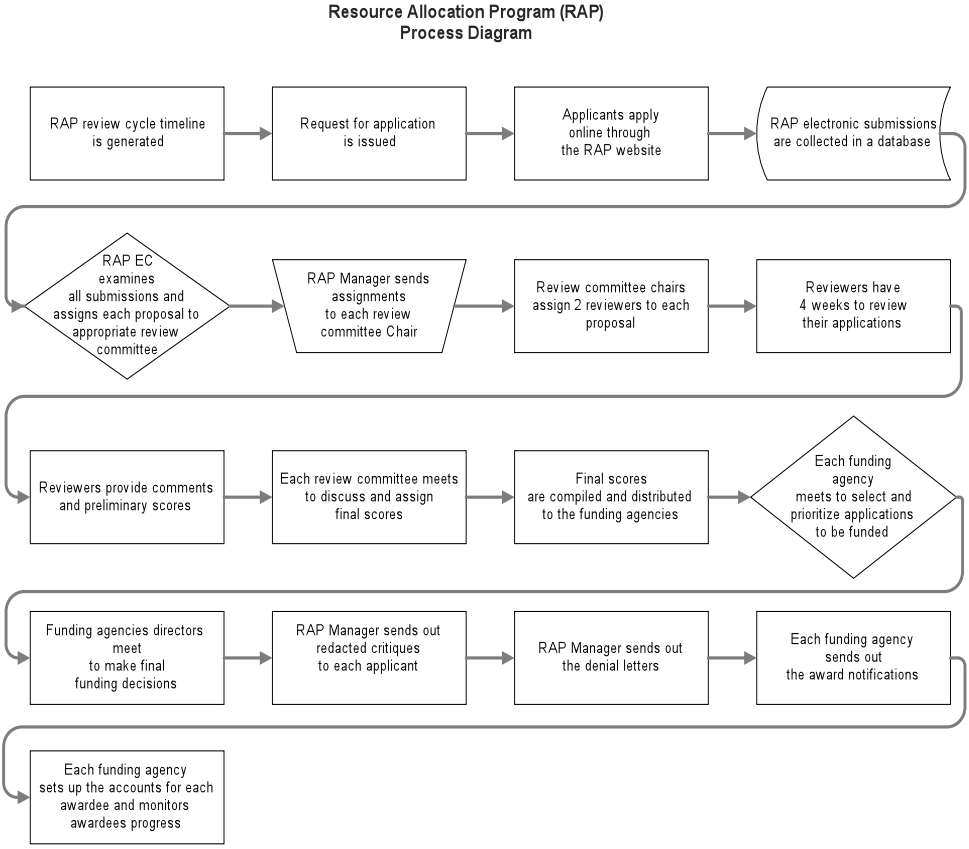
Figure 3. Sample Poster

RAP also supports a small number of "off-cycle" funding opportunities that are offered on an as-needed basis. In these cases, funding programs need to award their funds faster than the set deadlines of the main cycles would allow. Even in these cases, outside of the discrete cycles, the sponsoring programs are still able to leverage the RAP marketing strength as well as to utilize the same grant submission framework. The off-cycle grant opportunities, always offered as a single grant mechanism, are reviewed independently and do not use the RAP review committees.

Straight-forward, Easy-to-use Submission Process

RAP's application, review, and award management process is shown in Figure 4 below. The Request for Applications generally goes out six weeks before the application deadline. The Request for Applications defines the application submission time window for the electronic submission system (the "start date" through the "end date"). On the start date, the electronic application form is active and the website is completely updated.

Table 4. RAP Process Diagram



Every cycle is dynamic; new grant mechanisms can be offered and existing ones can be modified. New funding agencies can join RAP and existing agencies can decide which grants they want to continue to offer. The RAP Program Manager contacts participating programs and agencies ahead of the RFA announcement and asks them to review the website content relating to the grants they sponsor. Once this full assessment of all changes is done, the entire website content is updated using software engineering resources. The Program Manager is ultimately responsible for the deployment of a new and updated version of the website and electronic application before each new cycle is launched. In this way, any agency changes, e.g., types of grants offered or changes in eligibility requirements, are appropriately communicated.

Effective Website

The RAP website (http://rap.ucsf.edu), designed as a user-friendly, one-stop-shop for different intramural funding opportunities, is a significant resource for all users.

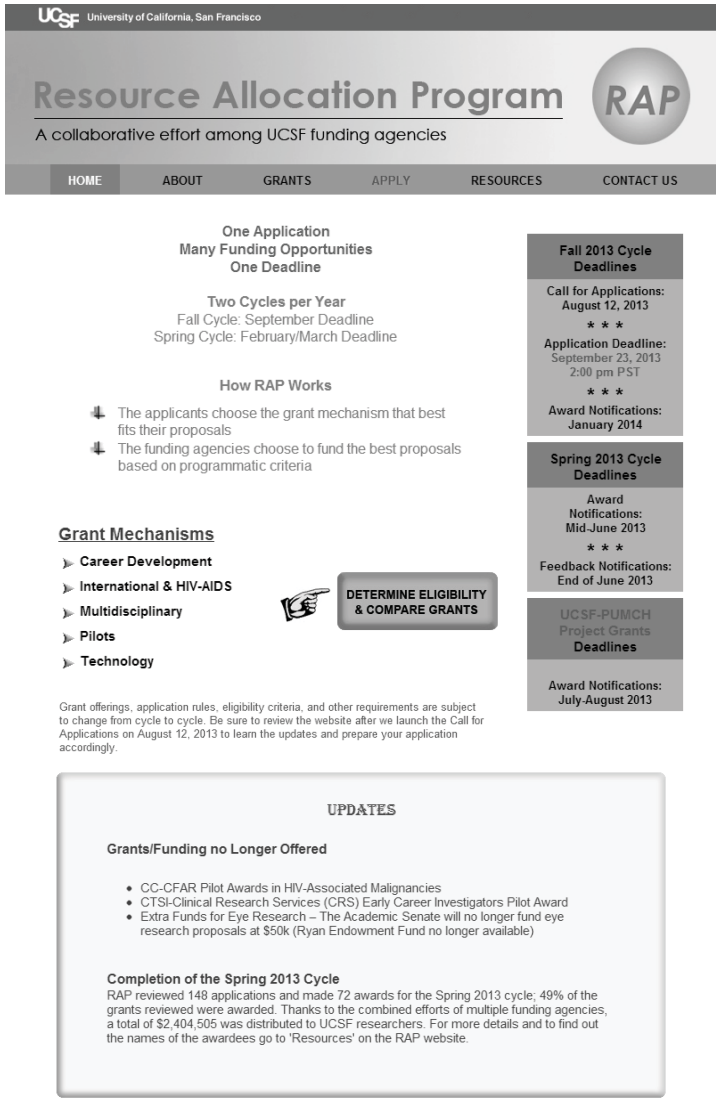


Figure 5. Screenshot of RAP Website Home Page

The website is organized into the following sections: HOME, ABOUT, GRANTS, APPLY, RESOURCES, and CONTACT US.

The HOME page, shown in Figure 4, highlights the program's slogan, "One Application, Many Funding Opportunities, One Deadline," and explains how RAP works. The page has information on RAP's major grant areas and links to other pages with information on current opportunities, eligibility criteria, and award amounts. The HOME page also features updates on important policy changes, new offerings, and any news pertaining to RAP. There is a well-defined, color-coded section that highlights funding cycle deadlines.

The ABOUT page briefly describes the program, mission, leadership team, and participating funding agencies. It also describes the RAP review process, and lists the standing review committees as well as all reviewers, without denoting their affiliation with a particular review committee. The GRANTS tab shows an overview of all grants offered, organized by major categories (Career Development, International, Multidisciplinary, Pilots, Technology). From this page, applicants can select each grant mechanism and find further specific information. The APPLY tab leads applicants to a step-by-step guide on how to submit a RAP application and includes an electronic submission form.

The RESOURCES page provides information on past awardees, program statistics, descriptions of success stories, sample proposals, and letters of support. Finally, the CONTACT US page provides contact information for the RAP Program Manager and the administrators of each participating funding agency.

One Simple Application Form

Applicants submit proposals to RAP via an on-line application form that is the same for all grant mechanisms offered. The application is designed to capture all information needed for the review and award process as well as for future reporting. The current application form has evolved over the years with the feedback and general consensus from all the funders. The program tries to balance the need to capture as much information as possible with the benefit of keeping the application within a reasonable length. Changes to the application form are driven by the common utility among the funders. If a new piece of information is useful to the majority of funders and applicable to most grants offered, then the implementation is deemed valuable.

Once all the required fields of the application form are completed, the applicant uploads the proposal as a single file in a PDF format. The proposals are written following mechanism-specific instructions, which are developed by the funders but harmonized to look similar and display the requirements in the same order so it is easy for the reviewers to identify missing or incomplete components. Any mechanism-specific proposal content is within the uploaded PDF file. After submission, applicants receive an email confirmation and have the opportunity to revise their proposals up until the submission deadline. RAP applications are submitted directly by the investigators who generally utilize their finance units or pre-award analysts to prepare the relatively simple budget. "Full-service," formal institutional grant administrative support is not needed.

Past the deadline, the electronic application is disabled and the review process begins. All electronic submissions are stored in a database and later downloaded by the Program Manager and placed in a common data repository to be available for review. The database allows two levels of administrative access: a basic administrative level granted to all support staff, and a higher administrative level granted only to the Program Manager that allows deleting and adding applications on an as-needed basis.

Comprehensive Expert Review

The RAP review process has been modeled after the NIH CSR study section review process (NIH, 2012), which is used to review NIH grant applications for their scientific merit, providing unbiased, expert assessments. The RAP review process uses 10 specialized standing review committees and draws from a large campus-wide pool of internal faculty, matching reviewer expertise with each proposal to provide a fair, peer-reviewed process that will encourage and stimulate research. This approach is possible at UCSF because it is a large institution with a broad spectrum of scientific areas represented. In a different setting the process might require the recruitment of external reviewers. It has been challenging to balance the benefits of utilizing senior faculty, who are more experienced, with junior faculty, who are more available and willing to serve. We try to achieve a good mix of senior and junior faculty. This balance also provides the perfect setting for mentoring opportunities. The review committee chairs are always senior faculty and expert reviewers. Finally, it is our goal during the reviewer recruitment process to have a good representation from all the schools: Medicine, Pharmacy, Dentistry, and Nursing.

Most applications submitted through RAP are assigned to a review committee organized by subject area. Currently, RAP manages 10 review committees. These committees are standing committees, each led by a chair and composed of UCSF faculty members. Each review committee reassesses subject areas, chairs, and membership on a yearly basis. Faculty members are nominated based on suggestions from the funding agencies, the chairs, and members of review committees. Nominees are also drawn from past awardees and other faculty who have volunteered for these committees.

Proposals are reviewed by at least two individuals with expertise in a closely related field and discussed by the entire topical review committee. Proposals are scored according to the review criteria delineated by the funding programs in the descriptions of each grant mechanism. Critiques are returned to the proposal Principal Investigator as feedback. Funding agencies choose to fund proposals based on the review comments, scores, and respective alignment with their programmatic goals.

The RAP review committees were formed according to the needs defined by the funding mechanisms offered through RAP and may be modified over time based on the proposals submitted. The program's goal is to establish a large pool of experts in various research areas and have all committee members be potential reviewers. However, depending on the number of proposals received and the reviewers' areas of expertise and availability, each reviewer will not necessarily review every cycle. Before RAP, each program could only use faculty reviewers who

were part of specific networks. The pools were small and often the match between application and reviewer expertise was far from ideal.

The RAP review process is perceived as fair by faculty leadership, reviewers, and applicants. Great attention goes to avoid conflict of interest during the review process, and chairs make a sincere effort to match each application with the appropriate expert reviewers. There is a strong commitment to provide a good review as each reviewer could be an applicant in the next cycle, and therefore everyone desires a fair process.

RAP Proposal Review Process

Review Committees

The RAP Executive Committee receives the full list of applications and can access all proposals via Dropbox®. The Program Manager makes the first attempt at assigning applications to the appropriate review committee. All resubmissions are reassigned to the same committee and to the same reviewers who did the review previously. The Executive Committee confirms assignment of each application to the appropriate review committee by topic. During the online submission, applicants can select the review committee, but the final decision regarding committee assignments is ultimately up to the Executive Committee and later confirmed by review committee chairs. Applicants are also given the opportunity to indicate one potential faculty member who should not review their proposal; chairs do their best to accommodate their request.

The chair of a RAP review committee plays a key role in the functioning and success of the review process. The chair and administrative support staff are responsible for managing the review process in compliance with RAP policy. The chair and support staff work in partnership to help facilitate a review process of the highest quality and fairness.

Review committee chairs receive and review the applications assigned to their committees and either agree with the assignments or suggest alternative review committees better suited in expertise. The review committee chair assigns two reviewers to each proposal, each equal in responsibility. The chair tries to avoid even the appearance of a conflict of interest and takes into consideration both the proposal PI(s) and the co-investigators. For RAP, being in the same department does not necessarily constitute conflict of interest. Faculty members with the same skill set most likely work in the same unit and are the experts needed for a good review. The general guideline for conflict of interest is that reviewers are in conflict if their research will benefit directly if the proposal is awarded, if they are in direct competition with the applicant in the research arena, or if they have a personal relationship with the applicant that may lead to bias. The larger the size of a review committee, the easier it is to manage the conflicts.

Once the reviewers' assignments are complete, support staff members contact each reviewer and provide materials necessary to complete the review of the grants assigned. This includes:

- a full list of all proposals assigned to that committee;

- customized review forms saved with a specific naming convention that makes it easy to retrieve reviews later. The review forms display the 1-9 scoring system used by RAP and scoring rubrics. Additionally, the forms have embedded any grant mechanism-specific questions that the reviewers need to address in order to provide a comprehensive review in alignment with research standards and funders' goals;
- a request to reply immediately if there is a conflict of interest so the proposal can be reassigned; and
- standard operating procedures (SOPs) developed to orient and guide chairs, reviewers, and support staff on the review process and on how to conduct the review committee meetings. The RAP review process SOPs are in alignment with the NIH review criteria and describe in great detail pre-meeting, meeting and post-meeting responsibilities to ensure consistency across the review committees.

Reviewers can access all applications assigned to their committee and previous reviews for the re-submissions. Reviewers are given approximately four weeks to review their set of proposals and assign preliminary overall scores based on the NIH scoring system. RAP does not ask reviewers to assign a score to specific review sub-categories as is done by the NIH CSR study sections.

Review Committee Meetings

Prior to the review committee sessions, the chair and support staff discuss plans and materials needed for the review session. The chair reads the reviews in advance of the meeting to facilitate the discussion, especially for those applications with a wide divergence in preliminary scores. An effort is made to have as many participants as possible attend in person with the option of teleconferencing offered as needed. The chair is responsible for ensuring each review is fair, equitable, and free of bias.

All proposals receiving a score of 5 or greater from both reviewers are triaged and not discussed, unless there are members of the review committee who would prefer to discuss them. The assigned reviewers provide their initial level of enthusiasm and concise reviews of the application with emphasis on its impact, strengths, and weaknesses. The proposal is then discussed by all committee members. Each proposal is given a final score by all non-conflicted reviewers in attendance (in person or by phone), including the chair. (These scores will be averaged to generate a single final score.) At the end of the meeting, scoring sheets are collected, and issues are either clarified or noted.

Post-Review Session Responsibilities

After the meeting, final scores are tabulated and results sent to the Program Manager. Reviewers' attendance and workload are tracked for all committees every cycle. Reviews for all the proposals in the competition are collected and reviewers' names and initial scores are redacted.

The Program Manager distributes the final results in a spreadsheet to the RAP committee (funding agencies). The sheet includes all applicants' names and proposals titles, the average

and standard deviation of the review committee final scores, and special notes. The sheet is organized by scores (from best to worse) and by grant category. The spreadsheet also contains charts with the distribution of scores among each committee and overall. Redacted reviews are made available to the funding agencies to facilitate their funding decision process.

Funding Agency Meetings

Using this list of candidate proposals and the associated final scores, each funding program plans its own internal meeting to decide funding priorities. During this meeting the funder discusses which proposals they would like to see funded, regardless of their ability to fund, and which proposals they would specifically prefer to fund. Funding agencies take reviews and scores into consideration along with how well a proposal fits their mission when deciding which proposals to fund.

The Cooperative "Horse-Trading" Session – Final Funding Decisions

One of the novel and valuable steps in the RAP process is the final funding session. All faculty directors and managers of the participating funding agencies, along with RAP staff, convene in person to make final funding decisions. The RAP Executive Committee chair moderates the session, calling every proposal in ascending order of score (best to worst) and asking who, among the funders, is interested in funding that application. The process is often referred to as "horse-trading" since it frequently involves trading one proposal for another to ensure all agencies meet their funding goals.

Our experience has shown that this meeting is remarkably successful in accommodating everyone's needs and allowing for a higher number of proposals to be funded. All funders come into the meeting with the goal of allocating their funds strategically and supporting as much good science as possible. This step in the RAP process significantly improves the likelihood of funding a strong proposal. Proposals submitted to one program may be picked up for funding by another funding agency because the topic of the proposal is relevant to that agency as well. Sometime proposals are co-funded by two different funding agencies.

After the meeting the results are circulated one additional time and agencies have a chance to review the funding decisions and make any necessary adjustments. If there are no issues, funding decisions become final and the funding agencies can start notifying their awardees while the RAP Program Manager sends out declination letters.

Applicant Feedback

At the end of each cycle, all applicants are notified of the outcomes and receive written reviews. The reviews are redacted so as not to reveal scores, reviewers' names or confidential comments. As has been observed before (Balaji et al., 2007), regardless of the funding outcome, this feedback is extremely valuable to applicants, especially for either their resubmissions to intramural funding opportunities or for subsequent extramural grant development. At the final step, the names of the awardees are posted on the RAP website along with the funding statistics for the cycle.

Costing Models

All programs on campus are eligible and welcome to use RAP to coordinate their funding opportunities via one of the two costing models:

Model 1: A full-service option that includes dissemination, submission, and review of proposals. Each program is charged based on the percentage of dollar amount funded in the prior academic year, i.e., their share of total cost is in direct proportion to the amount they awarded.

Model 2: A partial service option, where a funding agency uses RAP to publicize funding opportunities and administer on-line submissions. Costs are assessed on the basis of proposal submissions, i.e., there is a fixed charge per proposal submitted.

RAP has also served some programs by only advertising their funding opportunities at no cost.

A quick glance at the RAP budget will show that it is fairly lean and simple. It is composed of personnel expenses covering the Program Manager's salary and, in small percentages, the salaries of the other leadership members (RDO Director, RAP Chair and Vice-Chair). The budget also includes items such as honoraria for review committee chairs, computer support, marketing materials, and supplies.

The funding agencies that have used RAP recognize the added value and appreciate the services provided. Institutional leadership (Executive Vice Chancellor and deans of the four schools) has also recognized the value and benefits to the campus community and, in fact, partially subsidizes the program. The RAP model requires central support to succeed so that the costs are shared between the funding programs and the institution. Although RAP provides a huge value-add compared to what each single program alone could do, it can be too much of a financial burden, especially for the smaller programs, to pay for premium grant competition management services relative to other competing needs within their specific programs.

Implementation Challenges

Although the program founders had a clear vision and strongly believed that RAP would improve the management of intramural funds on campus, like in many process changes, there were some concerns. The funding programs and agencies were concerned that joining RAP would diminish their unique identity and perhaps even create confusion about their specific programmatic goals. The concern over programmatic identity was soon overcome by a simple marketing strategy. Agencies were represented on the RAP website and announcement materials with their names and logos, such that applicants easily identified the funding programs. The website continues to highlight the supporting funding program(s) for each grant mechanism offered. Some grant mechanisms are only supported by one funding program; others, e.g., the *Pilot for Junior Investigators*, are supported by several programs depending on the proposed project topic area and funder strategic goals. The Research Evaluation and Allocation Committee grants, for example, only support researchers affiliated with the School of Medicine and the Helen Diller Family Comprehensive Cancer Center requires faculty

applicants to be Cancer Center affiliates, while programs such as the Academic Senate have a broader funding target and fewer restrictions.

Another concern expressed by the early RAP adopters was that they might not maintain full autonomy over their funding mechanisms and awardee selection. This concern disappeared when programs realized they had full control over their research funding announcement content and grant descriptions. They were (and are) still able to determine independently key components of the grant mechanism, eligibility, review criteria, and award amount. They also provide grant-specific instructions that capture additional relevant applicant information. Occasionally RAP encourages funders to follow similar parameters when providing grant descriptions and instructions if that can benefit the applicants and the overall application process. In those cases, the applicant ease-of-use and positive agency outcome has significantly outweighed any small loss of funder-relevant application information. RAP has encouraged all the participating agencies/programs to focus on the big picture and think beyond the confines of their own programmatic goals to explore together what can be done for the sake of supporting good science and collectively helping out the investigators at our institution.

Administratively, it can be challenging to change "the old way of doing things." It is hard to change well-established methods and replace them with new practices. To that point, good communication between faculty directors and administrators has been a crucial and positive step forward itself. Successful process change requires an understanding of the change rationale, and the conviction that trying something new is worth it. During the initial implementation phase of RAP, we were fortunate that several funding program staff members involved were new, making things easier as no one was too strongly attached to old procedures. Inspired by the desire to implement innovation, the new and old funding program staff embraced the change to a centralized management structure. In addition, RAP maintains a strong "consortium nature," with scheduled collaborative discussion that includes participants at all levels of the process (see discussion below).

Finally, coordinating staff members who support the review committees but do not directly report to the RAP Program Manager or to the RAP central leadership requires tact and consideration. Central guidance is indisputably needed to keep the process consistent, but to make things work, it is important to establish a positive model of partnership and "managing without authority." Staff members involved need to buy-in and share the RAP programmatic goals, recognizing the value of each single contribution. Open communication is crucial so that all parties involved feel comfortable expressing their opinions, whether they be reservations or approvals. RAP management has worked hard through the organizational operations to empower each individual agency to speak its mind while encouraging everyone to keep an eye on each other's needs as well. By fostering respectful communication, RAP management strengthens the shared belief that a strong working relationship among the RAP participants is necessary to achieve institutional intramural funding goals.

Results

This model for managing multiple intramural funding mechanisms has been very successful, owing in large part to the founders' clear vision regarding the program's purpose and goals. The program is infused with a sense of shared responsibility and accountability to the greater good of research at UCSF. Stakeholders still maintain a strong sense of ownership and commitment, and are proud of this fruitful collaboration uniquely characterized by strong involvement of funders, faculty, administrative staff, and central campus leadership.

All stakeholders benefit from a more formalized, standardized application process. RAP provides an ideal infrastructure for sharing best practices, enables staff networking, and realizes administrative efficiencies and economies of scale. RAP is able to reduce overlapping administrative functions and, at the same time, provide additional administrative functionality. Importantly, RAP maintains funding agencies' identities, and provides increased visibility of smaller funding programs.

A significant benefit of the RAP process is that researchers have an increased likelihood of receiving research funding (compared to extramural funding), while the funding agencies often see increased funding of proposals of their strategic interest. This synergy is attained through the horse-trading session where innovative proposals submitted to one agency mechanism can be co-funded or funded wholly by another agency. In this way, RAP enables the funding of strong proposals within an agency's interest but beyond their usual budget limits, and it enables an increase in the necessary seed support for campus research programs.

Not only are intramural funding programs like RAP inherently valuable for enabling the generation of preliminary data needed for subsequent grant proposals, but they also enable the opportunity for applicant mentoring and proposal quality improvement (Balaji et al., 2007). RAP is no exception in this regard because it fosters mentoring within the review committee setting and enables proposal quality improvements via quality written feedback from the expert review process. Additionally, channels are created for networking of applicants with past awardees and review committee members.

Because the RAP review committees draw reviewers from the entire campus and hold single review committee meetings, they consistently offer broader scientific coverage, save reviewers' time and reduce their workload, and lower the potential for conflict of interest. This process also creates opportunities for mentorship of junior faculty reviewers. The expert review committee structure additionally enhances selection transparency and agency accountability for their funding decisions.

The RAP process provides tracking of all submissions, enables generation of statistical data on submissions, and stimulates agencies to revisit their goals/rules. RAP is working toward helping agencies in the evaluation and administration of awardees, e.g., tracking outcomes to evaluate the return on investment, facilitating progress reporting, and monitoring expenditure of funds.

Logistically, RAP offers other benefits to both researchers and stakeholders, including the fact that grant opportunities are easy to find as they are all in one web location, one application form fits all grant mechanisms, and there are two recurring cycles per year with a single deadline per cycle.

The program has grown steadily in support of different funding agencies since its launch in 2007. In FY2012-2013, RAP facilitated the award of $4.6 million to a broad spectrum of UCSF researchers. All four schools (Schools of Medicine, Pharmacy, Nursing and Dentistry) and the Graduate Division are routinely represented among the awardees, and a full range of biomedical research is supported through RAP funding. Due to its effectiveness and strong marketing strategies, RAP is now one of the most highly recognized programs on campus. Moreover, another program at UCSF was modeled after RAP, the Resource Allocation Program for Trainees (RAPtr), which was created to facilitate funding opportunities for students and trainees involved in research or innovation projects.

Figure 6 shows the growth in overall grant submissions regardless of the type of review (All Submissions) and grant submissions that utilized all aspects of the RAP submission and review process (RAP-reviewed Submissions). Of those grants that did go through the full RAP review process, the graph indicates the number of grants awarded per cycle and the total dollar amount awarded for that cycle.

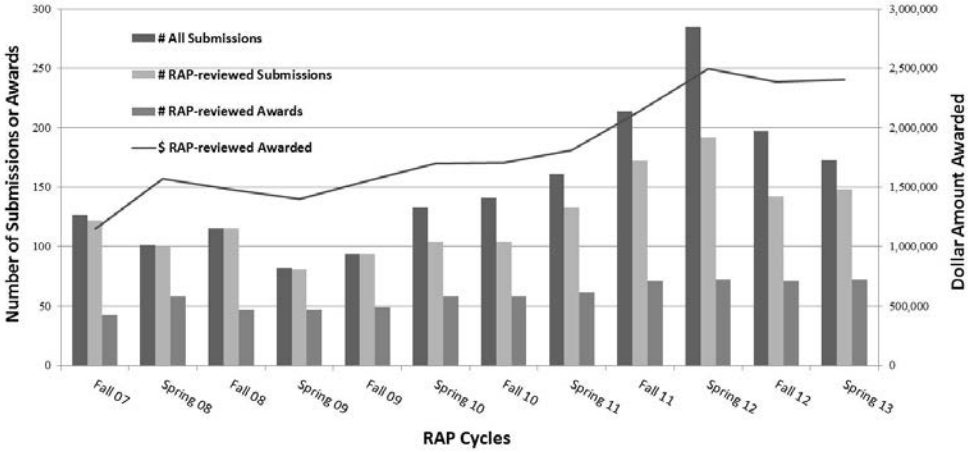


Figure 6. RAP Process Diagram

The centralized dissemination of funding opportunities not only connects researchers to potential funding in an organized, consistent, and simple way, but also provides university-wide visibility to the participating funding agencies. From the funding program perspective, this is certainly one of the biggest strengths of RAP. Table 2 shows the impact of RAP process management for one of the funding programs - the UCSF Gladstone Institute of Virology & Immunology Center for AIDS Research (CFAR). The number of applications received for

	Pre-RAP Management		Post-RAP Management			
Year	2006	2007	2008	2009	2010	2011
Number of Applications	16	14	25	37	47	46

Table 2. CFAR Grant Application Number before and after RAP Implementation

funding consideration nearly doubled after implementing RAP and its associated "marketing strategies." Anecdotally, this program also saw awards become more broadly distributed across the four schools on campus post-RAP implementation (data not shown).

RAP has also provided a structure through which funding agency programmatic data can be captured; prior to RAP most programs did not have the resources to track program performance metrics. Through RAP, funders now have access to more comprehensive statistics and have developed an awareness of the importance of accurate metrics. We continue to seek improvements in performance assessment.

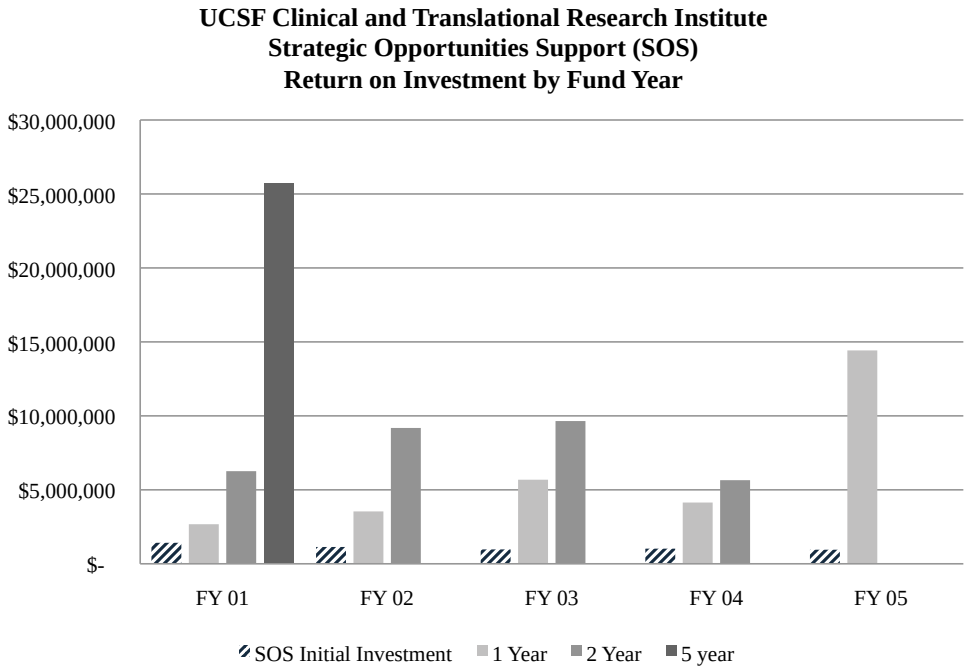


Figure 7. Return on Investment from the CTSI-SOS Program, one of the RAP funding agencies. The consistent and significant return on initial pilot funding program investment is largely due to the award of larger extramurally-funded grants.

RAP has facilitated the success of many on-campus funding programs such as CFAR and the CTSI-SOS Center. While it is hard to conclude what would have happened had an agency like CTSI-SOS not used RAP, it is evident that the investigators selected through the RAP process were successful at leveraging the results of pilot funding for successful bids to obtain larger extramural grant funding. Figure 7 shows the return on financial investment for the CTSI-SOS program, which has been able to parlay awards from RAP-funded grants into larger research awards worth six- to sixteen times more. Similarly, CFAR has reported that with an investment of $3,032,038 between 2007 and 2011, they have seen an increase in the numbers of K, R, P and U federal awards involving HIV/AIDS and totaling more than $135 million (see Figure 8).

	CFAR Pilot Awards	K Awards	R Awards	P Awards	U Awards	Total Awarded
Eradication/Latency	120,000	835,155	1,731,403	5,639,865	5,142,040	13,468,463
Biomedical Prevention	15,000	243,308	5,300,711	0	7,724,303	13,283,322
HIV and Women	465,000	1,161,036	6,370,934	2,858,691	16,274,838	27,130,499
HIV and Cancer	827,353	0	4,825,334	533,743	7,703,786	13,890,216
HIV and Aging	190,000	2,454,242	16,178,815	0	3,735,540	22,558,597
International	1,414,685	4,629,347	20,335,858	7,485,516	11,034,188	44,899,594
Sub-Total	**$3,032,038**	**$9,323,088**	**$54,743,055**	**$16,517,815**	**$51,614,695**	**$135,230,691**

Figure 8. Productivity from UCSF – Gladstone Institute of Virology & Immunology Center for AIDS Research (CFAR) Pilot Grants

The success of these programs can also be measured in the number of scholarly publications that have resulted from proposals funded through RAP. CFAR, for example, reports that between 2007 and 2011, 87 of these award recipients and mentees have contributed to 469 peer-reviewed publications related to their studies (Figure 8). Prior to RAP, the UCSF funding programs did not track much information, but have now matured through RAP-fostered discussions and have an understanding of the importance of implementing systems that allow for tracking and reporting. This illustrates another benefit of centralizing the management of intramural funding: all participants gain insight leading to improvements in operations not directly related to fund competition management itself.

Conclusion

The RAP intramural funding process offers a variety of benefits to both researchers and stakeholders. The existence of a centralized, coordinated program allows researchers to easily find funding opportunities and plan their grant-writing responsibilities, since the two cycle deadlines per year are recurring and predefined. The RAP grant format itself is also simple and consistent across multiple mechanisms. This ease-of-use helps investigators access

research funding at critical junctures in their research career, and is especially important because the funding rate for applications is usually close to 50%, much higher than most other funding opportunities.

Researchers can also benefit from the networking channels created through the program with past awardees as well as among review committee members. The RAP review process offers an ideal setting for mentoring of junior faculty reviewers by more experienced colleagues. The quality of the reviews produced through RAP is optimized because of the substantial effort done by the review committees to match each application with the most qualified expert in the field across campus. The feedback provided to applicants helps with both RAP resubmissions and grants submitted to other internal or external mechanisms.

Applicants are not the only beneficiaries of the system, however. The consortium nature of the RAP process enhances transparency and accountability of all parties involved, challenging all to operate at their best, to have an open view on issues, and to rethink and continuously improve their processes. Stakeholders, such as the funding agency staff and faculty volunteers, also gain from RAP and they recognize the added value: RAP provides a more formalized and standardized process that leads to more consistent reviews and funding decisions. All participating agencies are now able to track all submissions (funded/non-funded) and can generate statistical data for reporting purposes. This consortium process constantly stimulates agencies to revisit and improve their goals and rules, and provides an excellent infrastructure in which they can share best practices and find opportunities for networking among themselves.

The next big step in the RAP program development is implementing a robust electronic solution that will not only enable efficient submission, review, award and tracking of proposals, but robust management and reporting as well. We are now ready to streamline the review process and decrease the administrative burden through a cost-effect electronic system. The award process, handled by each agency, can also be improved. If all data, from submission to award, is kept in the same system, RAP will be able to facilitate the development of reporting best practices for all participating funders. Identifying and developing such a tool and implementing it successfully are our next big challenge.

One of the program's biggest strengths has been the stakeholders' clear vision and cooperative behavior. It is our hope that RAP will be seen as a model and will inspire other institutions, big and small, to consider implementing a centralized intramural funding management program. Although the RAP process cannot be described as simple--it is actually more complex than the singular processes used in the past by the separate agencies--participants agree there is essentially no redundancy of work and every single effort is driven by a strong purpose. The deans and the Executive Vice Chancellor have recognized the value-add of a centralized management mechanism and are fully supportive of the program, recognizing that it strives to guarantee transparency, fairness and efficiency while maximizing the investigator potential for funding. Together, the RAP staff and associated consortium of funders and faculty do more and try to do it better – truly a great example of on-campus synergy and teamwork.

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Research Synergy: The Graduate School of Public Health, the SDSU Research Foundation, and San Diego State University

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Abstract: *The evolution of a research university can take many paths. Described here is a case study of the synergy between the establishment and growth of a primarily graduate school and the commitment to developing a research university, all with the assistance of a separately incorporated non-profit research administration entity. The result has been a dramatic advancement of the university as a nationally recognized research institution, benefiting from an emerging field and school focused on applied research and community engagement, and a research support entity that has likewise thrived in its mission. The strategies leading to this success highlight the role of research in institutional advancement and regional recognition, even when operating in the context of a primarily teaching oriented state educational system; the support of a strong research management apparatus was key to producing successful results.*

Keywords: *research university, strategic plan, research management*

Introduction

The evolution of San Diego State University (SDSU) from a state teacher's college to a true research university has followed a remarkable trajectory, accelerating dramatically over the past thirty years. SDSU is Carnegie classified as a research university, high research activity. The Carnegie classification from the Carnegie Foundation for the Advancement of Teaching is a widely used framework for describing institutional characteristics in higher education. In particular, the classification is often utilized to provide a measure of research commitment and productivity in higher education institutions. Many other aspects of these classifications are also utilized in other kinds of studies and interpretations. The classifications and components have been refined and revised numerous times over the years. The Carnegie classification for doctorate granting universities includes three principal classifications: doctoral/research universities, research universities/high research activity, and research universities/very high research activity.

Many universities strive for prominence as primarily either teaching or research institutions. Over the past decades, however, the importance of a dominant research profile has gained wider acceptance. Research support implies excellence, is particularly critical in attracting high-quality faculty and graduate students, and increases visibility to various constituencies and especially to donors. Many primarily teaching institutions have worked hard to increase their research visibility and measurable successes. Traditional research institutions have worked hard to stay on top. And many more institutions have nudged the pendulum closer to research from the teaching end of the continuum.

The establishment and growth of SDSU's Graduate School of Public Health (GSPH) parallels the changing priorities of the university in responding to these national trends, and provides a case study of a strategic move towards research and graduate education. The GSPH's contributions to the community, including educational diversity and an increased supply of healthcare professionals, the conduct of applied research, and community service provides benchmarks against which the mission of SDSU and the university's research apparatus, constrained by California laws governing higher education, can be assessed.

The purpose here is to present a case study of how the creation and development of the GSPH at SDSU paralleled, or perhaps even led, the evolution of the university into a more prominent research institution, facilitated by a separate research management organization, a shift consistent with the promotion of the research role of major universities (Kirwan, 2010). The GSPH was one of the most prominent new academic initiatives within the university created entirely from scratch over the past 35 years. The school is either an instigator or a benefactor, or both, of a significant and intentional redirection of the strategic priorities of the university. The arrival of SDSU's current and eighth president, and the concurrent development and implementation of a new strategic plan, is a further extension, refinement, and reaffirmation of these earlier historical trends. All of this occurred in the context of an educational system that is not oriented toward faculty research, and that required the catalyst of a successful separate research management organization, representing an unusual alliance of forces coalescing towards a common goal.

This case study then is about the convergence of two interconnected stories, one about an educational unit within the university and one about a separate but affiliated research management organization found in some other graduate and research organizations, but not as common in comprehensive universities. This particular model worked effectively in the context presented here. In the interests of creating realistic expectations, however, there is no one universal model to fit all situations (Taylor, 2006). But the model presented here provides insight into one approach and suggests the need to explore many options in the establishment of strategic directions and operational planning when the institutional goal is to expand and support the research enterprise in a teaching environment with limited financial resources.

This case study is based on the author's longitudinal observations from 1981 onward. The author is a cofounder of the GSPH and the principal founder of the healthcare management program. In his role as a faculty member he has been principal investigator on approximately $2.5 million of grants, primarily awarded from the U.S. Health Care Financing Administration (now The Centers for Medicare & Medicaid Services) and the U.S. Centers for Disease Control and Prevention. As a principal investigator, the author has had extensive experience on the grantee side. Over the past eight years the author has been in a purely administrative position in the College of Health and Human Services (CHHS) with duties that have included oversight of all grant and contract activity at this level and college approval authority for proposal submissions. As a result, the author has worked extensively with the San Diego State University Research Foundation (SDSURF) and other components of the university from both the academic researcher and university administration perspectives. All of this experience occurred during the evolution of the university into a significant research institution.

The Academic Setting

The university was founded in 1897 to educate elementary school teachers (Starr & Polkinhornm, 1995). The university became a four-year public state teachers college in 1921. The mission expanded beyond teacher education training in 1935, and San Diego State became part of the newly created California State University (CSU) system in 1960 with the reorganization of higher education in California. Interestingly, according to former University of California (UC) President Richard Atkinson, SDSU was at one time approached to join the UC system but that initiative never materialized (Atkinson, 2012). San Diego State became a university in the early 1970s. Although set in a teaching oriented educational system, SDSU has long strived to be a hybrid of teaching and research, with quality in both arenas (Vincov, 1997).

Throughout its history, the predominance of students graduating from the university have remained in Southern California. The 280,000 alumni include many San Diego city and county elected officials, many senior administrators in business and in the nonprofit sector, and a number of senior executives of well-known national and international corporations. Prominent sports and artistic stars are also included in the alumni ranks. Over the last 30 years, SDSU has evolved into a large and highly diverse entity. The university currently enrolls approximately 33,000 students in 90 bachelor's, 78 master's, and 22 doctoral programs (San Diego State University, 2013a). Graduate student enrollment and program and post-graduate expansion has paralleled expanded faculty research.

By Fall 2013, 56 percent of students were female. By ethnicity, whites comprise about 40 percent of enrollment, Mexican-Americans and other Hispanics approximately 30 percent, African Americans just under four percent, and various Asian ethnicities comprise most of the remainder (San Diego State University, 2013a). The faculty complement includes approximately 710 tenure-track faculty and approximately 650 full-time and part-time lecturers; total faculty and staff employment is nearly ten thousand including auxiliary organizations. The physical campus has grown over the years as well with new facilities worth over $430 million added during the past decade alone. Development activities have also accelerated and the university is currently in the public phase of a $500 million fundraising campaign.

SDSU is comprised of colleges and within each college are departments and schools. School directors and department heads report to the deans of colleges, who in turn report to the Provost, the university's chief academic officer. The Provost, along with the heads of the divisions of Business Services and of Student Affairs, reports to the president. The GSPH is a unit of the CHHS which was created in 1978 to consolidate health related programs. The CHHS includes the Schools of Exercise and Nutritional Sciences, Social Work, Nursing, and Speech, Language, and Hearing Sciences. For Fall 2013, the college enrolled approximately 5,000 students, of whom approximately 1,000 were graduate students. The CHHS functions as the "health sciences center" for the university with an additional goal of promoting research collaboration and teaching efficiencies.

Elliott Hirshman became the eighth president of SDSU in 2011. His goals are to emphasize academic excellence, student success, community engagement, diversity, and

internationalization. His background includes conducting research in experimental psychology and serving as Chief Research Officer for a large East Coast university. President Hirshman, in addition to the provisions of the strategic plan, has already committed both state and non-state (soft) money resources to improving the ability of faculty to obtain grants and contracts, and has supported the hiring of additional faculty in clusters of expertise to build upon the university's existing research areas, a key commitment to continue and expand the trends discussed here.

The Research Foundation

Since 2000, university affiliated entities have administered over $1 billion in grants and contracts. Unlike most research universities, the CSU system maintains separate legal entities for non-state funds. Like many other CSU campuses, administration of extramural support, including grant and contract funds, non-state real estate holdings, and donations is conducted by the SDSURF, an auxiliary 501(c)(3) organization. The sole stated core mission of the SDSURF is to administer the university's grants and contracts, and to provide space for research programs. The SDSURF was established in 1943 and currently administers approximately one thousand projects with annual revenue exceeding $150 million. Approximately 160 support staff and 2,500 project employees work for the SDSURF. SDSURF staff provide the usual array of research support functions including grant and budget development, grants administration, managing physical facilities encompassing over one million square feet of commercially leased and owned research project space, technology transfer, legal services, risk management, audit, and administration of most university endowment funds, and manages accounts for San Diego's public radio station which is located on the SDSU campus. The SDSURF is a fully integrated operating entity with its own financial and human resources management and leadership.

The SDSURF operates under provisions of the California education act, Code of Regulations Title V, and other relevant regulations, operating agreements, federal and state tax authority as a federal Exempt Organization, and CSU Executive Orders. All such auxiliary organizations are under the ultimate responsibility of the university president. Authority for the establishment of auxiliary organizations recognizes that under California law certain state institutions need functional ability to conduct activities that do not fall within the authorization for state side operations. Recognize also that campuses of University of California and of the California community colleges are operated under their own separate state and administrative authorities and different rules apply. Complex regulations apply to the transfer of funds between auxiliary organizations and the university. SDSURF resources can ultimately benefit the university on a fiscal basis. Much university entrepreneurship operates under the authority of the SDSURF, separate from the state, primarily instructional, side of the university. This platform provides a very sympathetic approach to such efforts.

Faculty conducting research manage their extramural funded projects through the SDSURF rather than through the university itself. Grant and contract supported faculty who are paid on their research projects may receive supplemental pay from this "second" employer. Mechanisms exist to "buy-down" state teaching obligations. The university also maintains an additional

501(c)(3) entity, the Campanile Foundation, for managing donations and for development and capital campaign activities.

The university and the SDSURF have extensive governance and administrative connections. The Board of Directors of the SDSURF includes university officials and selects the chief executive officer. Another close connection involves the SDSURF and the university's Office of Graduate and Research Affairs (OGRA), which is headed by a Vice President for Research and Graduate Dean who is heavily involved in policymaking decisions regarding the SDSURF and its resources. The SDSURF's mission is closely aligned with that of the university, and especially of the OGRA. The SDSURF generates specific support for faculty research and investments in new university initiatives. Ultimately, the OGRA, its Dean, the deans of colleges, the Provost, and the President determine the research direction for the university. The SDSURF carries out these directions but generally does not initiate policy development with regard to research priorities and institutional spending.

The SDSURF also provides a connection between university researchers and industry. This tie-in has been beneficial in terms of both specific project support and university development efforts. The SDSURF's technology transfer office facilitates translation of research into proprietary products and provides revenue streams from faculty research activity.

The School of Public Health

The origins of the GSPH trace back to the late 1970s when the university retained John J. Hanlon, M.D. to prepare a vision for its health and social services programs. Dr. Hanlon was a retired Assistant Surgeon General of the United States Public Health Service and one of the fathers of modern public health. Dr. Hanlon recommended the establishment of the GSPH to provide a new focus for the university's community commitment and to ignite research activity. His proposal was warmly received by university President Thomas B. Day, a physics researcher himself. President Day gets the credit for both moving the university's strategic thinking toward a research agenda and for supporting the development of the GSPH. The graduate research dean at the time also played a key supporting role. In his oral history for the university, Dr. Day reports that he felt that the establishment of the GSPH was a very successful operation. He noted that he had to protect funds for the new school at the same time he was cutting back elsewhere, and that was a difficult situation (Resnick, 2006). The Chancellor of the CSU, Glenn S. Dumke, concurred with the establishment of the GSPH and of the CHHS as an administrative superstructure to focus the health related programs and research of the university.

The GSPH began faculty and administrative staffing recruitment in 1979, first hiring a school director followed by division heads for programs in health services administration, maternal and child health, occupational and environmental health, and epidemiology and biostatistics. The next year, the program in health promotion was initiated. Faculty recruitment occurred fairly rapidly to staff up the new divisions and programs.

Although the initial concept of the school was graduate only education, when the state fiscal crisis of the early 1990s occurred an undergraduate unit related to public health was folded into the school and became the basis for a now popular major. The initial strategic plan for the school centered around accreditation by the Council for Education in Public Health (CEPH), the specialty accrediting body in public health, obtaining university resources, and the development of a broad and strong research agenda by the newly hired faculty. From the outset, research was expected to be a high priority and a productive result of university's investment in this new endeavor. The school was fully accredited in 1985. The program in healthcare management received its first accreditation in 1982 from the Accrediting Commission on Health Services Administration, now the Commission on Accreditation of Healthcare Management Education.

Although SDSU had already established a research orientation among its younger faculty, and an interest in the healthcare arena, there was significant opposition to the creation of the new school. This opposition focused primarily on the potential diversion of resources, and especially of faculty positions, that might occur at the expense of other units in the university. In a generally always constrained fiscal situation, this is a fairly rational attitude. Support and pressure from the university president and the graduate dean, and from sympathetic faculty, eventually led to GSPH approval and acceptance on campus. Subsequent success in attracting extramural support through the SDSURF, especially for research projects and cross disciplinary collaboration among campus units, contributed significantly to gaining political support for the school.

One strategy used in the initial stages of the school's creation to gain rapid national recognition and a jump in securing research dollars was to attract a mix of older, very established faculty and leadership, and younger people. The more established faculty provided name recognition and credibility. In this group, for example, was the former dean of the University of Pittsburgh School of Public Health, a specialist in environmental epidemiology. Another early faculty member with international fame was an infectious disease specialist who edited six editions of the definitive book on communicable disease, a handbook that has been published since 1915. There was some risk in this approach in that attracting individuals who might want to semi-retire rather than work hard would dilute the productivity of new faculty positions. As things turned out, the new "older" people were productive as measured by extramural funding (SDSURF, 2014) and publications (GSPH, 1984). So the strategy was ultimately quite successful, and facilitated attracting other faculty and research funding. This strategy might have also helped divert some of the opposition to the school, given the intimidation factor associated with new faculty with international fame.

Acquisition of physical space is usually challenging in universities. State provided facilities located on campus have generally been at a premium owing to the many competing needs of the campus community and limitations on availability of capital expenditure funding for building construction and renovation. The GSPH began in a very small building at the edge of campus and has since grown into larger space in some of the oldest and most historic buildings on campus, totaling around 10,000 square feet. The school currently conducts its extramurally funded research activities in approximately 53,000 square feet of off-campus

space provided directly or rented by the SDSURF, a significant advantage in having a non-state resource for research space which allows more flexibility and perhaps more rapid responses to needs. These research facilities are scattered around San Diego County, including physical locations in the South Bay, and also space in Imperial County for projects operating there. Wet labs for instruction and research are provided on campus and are utilized mostly by the Division of Environmental Health. Equipment has generally been generously provided over the years through various state funds and supplemented by research funding. State funds for equipment are primarily justifiable for teaching purposes, but once installed equipment can also serve a secondary research use, especially when students are involved in faculty research. For example, the SDSURF generally does not provide wet lab facilities so this is an area that typically falls into the state support side even when partially used for faculty and student research. Parenthetically, the SDSURF has helped to finance some on-campus construction directed toward research and administrative use.

Research and Doctoral Education

Conceptualization of the GSPH recognized the key role of research and doctoral education in a primarily graduate entity. Faculty recruitment and incentives were biased in favor of promoting a broad research agenda. The GSPH has a number of large research centers, which focus on specific research areas and are led by key principal investigators. In the fields forming the basis of public health, research is primarily an applied enterprise so that many of the research endeavors require working with community groups and organizations, and the study of population-based issues. This research orientation facilitated a more direct involvement in the community than might be typical in basic research fields.

The growth of research is best exemplified by grant and contract revenue generated by faculty. Grant and contract revenue includes all extramural funding ranging from graduate student training to wet laboratory bench research. Table 1 presents contract revenue from 1987 through 2013, all of which has been channeled through the SDSURF, for SDSU, the CHHS, and the GSPH.

Years	SDSU	CHHS	GSPH	GSPH as a percent of SDSU
1987-1990	$119,517,304	$15,809,037	$11,013,233	9.2
1990-2000	$872,064,717	$193,761,877	$149,722,811	17.2
2000-2010	$1,302,447,439	$379,180,773	$184,571,300	14.2
2010-2012	$272,612,916	$85,719,963	$50,683,497	18.6
2012-2013	$115,708,473	$34,833,140	$20,182,441	17.4
1987-2013	$2,682,350,849	$709,304,790	$416,173,282	15.5

Sources: Data derived from an internal report, "Summary of Grant and Contract Awards," San Diego State University Foundation through 1998, and "PI Profile, Proposals and Awards," the internal data system of the San Diego State University Research Foundation.

Table 1. Extramural Grant and Contract Funding through the SDSURF, SDSU, CHHS, GSPH, 1987-2013

More critically evaluative is the revenue per full-time equivalent tenure track faculty member that, for the CHHS in many years, has exceeded that of any other college within the university, and all other CSU campuses. For example, for the 2012-2013 fiscal year, the CHHS had extramural grant and contract awards of $442,999 per position as compared to the College of Sciences' $267,802. For fiscal year 2012-2013, GSPH faculty were five of the top seven recipients of extramural support for all of SDSU, including the top two, and were the top two recipients of indirect funds as well. The GSPH has consistently accounted for half or more of the CHHS's extramural revenue, and an average of fifteen percent of SDSU grants and contracts over twenty-six years with roughly just over four percent of SDSU full time state tenure track faculty lines. The indirect attributable to these projects, in turn, provided significant support for SDSURF operations and facilities during this time period. In recent years the CHHS has accounted for 20-25 percent of SDSURF indirect operational and facilities support.

With regard to doctoral education, a topic closely aligned with research, the CHHS offers four Ph.D. programs, three of which are in the GSPH (epidemiology, health behavior, global health). Doctoral education typically feeds on faculty research and both agendas cross-pollinate each other. The doctoral program initiatives were also driven by accreditation requirements. It is worth noting that the evolving field of public health offers opportunities for doctoral level professionals to assume both academic and applied workplace positions such as in public health agencies and in industry.

Doctoral programs have been a natural area for growth. SDSU has long prided itself on the number and quality of its doctoral programs. The evolution of doctoral education in the GSPH paralleled that in the university and provided a further avenue of support for the university's evolving ambitions. California law requires that CSU campuses offer Ph.D. education jointly with another university. The natural combination of the GSPH and the medical school at the University of California, San Diego (UCSD), Carnegie classified research university (very high research activity), particularly its Department of Family and Preventive Medicine, led to extensive collaboration with multiple foci. The core basis for this collaboration has been the joint doctoral programs. Other collaboration involves research activity and a preventive medicine residency program. UCSD research is administered on a traditional basis, although UCSD also operates a 501(c)(3) foundation, primarily for development and endowment management.

The three doctoral programs within the GSPH are well established. Graduates receive the Ph.D. degree issued by the University of California and the California State University jointly. Graduates of all three programs have quite successfully obtained employment. Doctoral students have played a key role in many of the research projects undertaken by faculty and are extensively involved in research at both SDSU and UCSD. They may be employed as teaching assistants on the state side or as researchers on funded projects through the SDSURF. Doctoral education is highly dependent on the existence of a successful research program. Beyond doctoral programs, the principal focus of GSPH education has always been on the master's degrees, particularly the Master of Public Health.

In addition to joint doctoral programs for the Ph.D. degree, the CSU has sought authority for independent professional doctoral degrees. These degrees are practice, rather than research, oriented. The first of these degrees at SDSU has been the Ed.D. in education. The CSU system has gained independent authority to offer the Doctor of Nursing Practice (D.N.P.) and the Doctor of Physical Therapy (D.P.T.). The CHHS now offers the D.P.T. degree in the School of Exercise and Nutritional Sciences. The further expansion of independent doctoral degrees is a highly politicized issue subject to debate and decision-making by the state legislature. The University of California has historically sought to limit doctoral education within the CSU. Whether the CSU will further expand independent doctoral education, including most controversially the Ph.D., has yet to be determined. This issue is part of the eventual re-examination and potential restructuring of Title 5.

Diversity and Research Priorities

Diversity has long been a priority at SDSU. Diversity means access to education and professional careers for students from traditionally underserved backgrounds, producing professionals to serve populations and communities lacking such resources, and contributing to the improvement of lives in all regions of the nation through applied research. Demographic trends over the past fifty years, if not longer, especially as regards immigration, have produced highly diverse populations in California and throughout the United States and the world.

SDSU is a highly diverse university with nearly 60 percent of students designated as nonwhite and recognition as a Hispanic-Serving Institution. The CHHS and the GSPH are both highly diverse as well. Approximately 80 percent of the college's student body is female, and 60 percent is nonwhite. The diverse student body includes many first time college students, and families with economic and cultural disadvantages. Numbers for the GSPH are similar. The programs offered by the college target large diverse populations and underserved regions. This is particularly true for the schools of social work and public health. Much of the research agenda in public health is focused on historically minority populations, border health, health disparities, and environmental health concerns, especially along the U.S.-Mexico boundary.

The GSPH encourages diversity content in its educational programs as well. For example, all GSPH undergraduate students must complete an international experience (Daly, Baker, & Williams, 2013). The CHHS may be the first and only college of health and human services in the United States with such a requirement for all students at the undergraduate level. Many courses include content relevant to cultural competency, health disparities, disease patterns, and populations at risk, and build on the diversity-focused research conducted by faculty through the SDSURF.

Community Engagement and Applied Research

The university is noted for its ties to the community. Sixty percent of alumni live in San Diego County. This is especially evident in such fields as education, social work, nursing, and business.

The town and gown distinction dates back to the middle ages and today is often used to reflect the extent to which a university is oriented or integrated into its local communities. Pure research institutions tend to be less community oriented while broader based and more diverse institutions, such as SDSU, are typically much more heavily invested in the community. In the town-gown continuum, SDSU trends toward the town side while UCSD, a very traditional research university, falls on the gown side. Community engagement takes many forms. The GSPH has extensive community involvement through student internship programs at both the undergraduate and graduate levels. Students at the graduate level, conducting master's and doctoral research, frequently utilize community settings for their projects.

Technical expertise is sometimes provided directly by faculty members on a consulting basis, but the GSPH also recognized early on the need for more substantial formal opportunities to work with community organizations. As a result, and with federal and state funding opportunities, the Institute for Public Health (IPH), an applied research center managed through the SDSURF, was established as a community technical assistance and information translation entity within the school. The IPH provides project-based technical assistance and also conducts applied research. In recent years, and with dynamic leadership, the IPH has generated about $30 million of grant and contract activity. The role and status of such units within a research university setting is somewhat controversial in that the work that is typically done is extremely applied and designed to facilitate the operation of community organizations and local governments, rather than to focus on traditional publishable research. Some research universities have spun off these types of units into separate independent research or consulting entities. The SDSURF, owing to the policy focus on research activity being based in the university, is neutral on such entities as long as they generate adequate indirect support for their operations and facilities, which do not receive any state subsidy.

Any comprehensive quantitative measurement of the impact of all of these forms of community engagement in the San Diego region is not available and would be quite difficult to compile. Clearly community involvement has been, and continues to be, substantial, and recognition of the school regionally and nationally for this has occurred. A report prepared for the office of the Chancellor of the CSU estimated the economic impact of each campus. SDSU is estimated as of 2010 to have annual economic impact of over $1 billion on the regional economy and $1.5 billion on the statewide economy (ICF International, 2010). But community engagement can be at least partially measured by numbers of graduates and positions in community organizations. The GSPH has graduated and placed significant numbers of professionals in the healthcare industry in the San Diego region and elsewhere. In addition, many students have received their degrees, especially at the master's level, while working full- or part-time and have utilized their education to advance in their own organizations.

To a lesser extent, community engagement also includes faculty involvement in local healthcare organizations. Faculty have provided advice, technical assistance, and leadership in various ways in the local community, often drawing on their research reputations and experience. Since community service is at least partially rewarded in promotion and tenure decisions, although

not to the extent of research and teaching, there is some incentive to participate in these types of community activities, and, of course, as mentioned previously, community engagement and applied research serve each other's needs, and often these efforts result in research collaboration and grants. All of these aspects of community engagement are also highly consistent with the university's regional focus and current strategy of addressing community needs and of appealing to the San Diego region, in a sense as "San Diego's university."

The Process of Research Enhancement

The political and administrative processes utilized to move the university's research agenda have been alluded to throughout this discussion. Some additional elaboration is warranted to provide a more comprehensive perspective on how this goal was achieved. It is important to recognize that within the CSU system, research is essentially not funded and is not considered a core mission by state law. Therefore, there is little or no provision for infrastructure to support research activities including research management capability, seed money and financial support for faculty project development, faculty time allocation for research endeavors, doctoral student support, and a support structure to reward research success. All of this had to be created to the extent possible over a period of time.

The infrastructure component required the establishment and maintenance of a separate legal entity as described in this case study. State resources and the state operational mechanisms for financial management and other aspects of what would be necessary for grant and contract administration did not exist. Hence the creation of the SDSURF provided this infrastructure.

Second, faculty needed to be incentivized to conduct research and to seek extramural funding. Financial rewards were created within the grant management apparatus to allow additional pay for faculty conducting funded research. Faculty were provided release time from a typically relatively heavy teaching load expectation for research activities based on potential for publishing and for attracting extramural grants and contracts. Limited resources were allocated for seed money for research activities. As the SDSURF increased in size and scope, a greater quantity of resources were available to provide seed money for faculty. Some limited state resources were also available. Again, by way of comparison, within the UC system research is a mandated priority and more extensive resources are available for this purpose.

Of course, the ultimate mechanism for achieving an enhanced research agenda is to attract research oriented faculty for state tenure-track positions. This became a significant priority, eventually allowing for the accumulation of a critical mass of research faculty. This led to accumulations of faculty in specific areas who as a group were highly successful in attracting a large volume of grant and contract funding. These individuals needed to be recruited away from traditional research universities by providing financial and other incentives and an increasing group of like-minded academics to work with. The addition of doctoral programs also provided a point of attraction for many faculty given that doctoral students are a valuable source of researchers on projects.

Discussion and Assessment

A new strategic plan for the university, *Building on Excellence*, was published in 2013 (San Diego State University, 2013b). The plan is intended to cover the five years through 2018. Three primary areas are addressed: student success, research and creative endeavors, and community and communication. The area of student success focuses, among other things, on continuing widely recognized progress achieved in four-year graduation rates; improving the student experience, both educational and social; and transforming the educational experience through the establishment of an honors college, additional financial support, international experiences for students, and educational innovation. The research and creative endeavors goals include increased funding for research activity and support for grant development, support for an expansion of the arts, and an increased focus on applying the research orientation of faculty toward both undergraduate and graduate education and student involvement. Community and communication focuses on engaging alumni and community supporters, enhancing the campus environment, developing activities and relationships to support the San Diego region, and expanding public communications to improve awareness of the university's successes.

One measure of implied status is national rankings. U.S. News & World Report recently named SDSU number 14 on its list of up-and-coming schools (U.S. News & World Report, 2014). The Washington Post recently reported that SDSU increased its overall rankings the most of any university in the country since 2011 (Anderson, 2013). Various programs within the university have achieved notable rankings within their own fields; these include, for example, international business, audiology, rehabilitation counseling, clinical psychology, and the College of Engineering in different listings. Research reputation is clearly an extremely key component of overall reputation for many universities and the expansion of research funding is essential to building name recognition, especially for a large state university. While rankings are highly unreliable and may be of questionable validity, they do have some recognized correlation with measures of quality and appearing on these radar screens is important to national recognition (Sweitzer & Volkwein, 2009).

With regard to those aspects of the strategic plan that focus on research, the university is already committing funding for additional faculty positions in strategically selected fields, and is investing university funds to expand support of research activity. Parenthetically, the current university president's previous role as a vice president for research assures his extensive knowledge of, and experience with, university and faculty research, the single most notable achievement associated with adding the GSPH to the university and the most important facilitating role of the SDSURF.

The GSPH has been a stimulus through faculty campus-wide and inter-institutional collaboration on health services research, epidemiology, and other scientific inquiry. The SDSURF helps to provide collaborative opportunity and breaks down barriers between disciplines and schools and departments since it is an impartial research entity hosting institutes and cross-disciplinary grants. The SDSURF is a neutral party whose interests are simply derived from promoting all funded research opportunities.

The integration and leadership provided by an external nonprofit auxiliary organization also demonstrates that this model can be effective in promoting a strategic research agenda in a state university setting. While not typical of many research universities, the provisions of California law required the use of this approach and the result has been highly successful at SDSU and at other CSU campuses with similar constraints. Having a separate legal entity for the conduct of research has facilitated increased faculty research pay, a higher share of indirect cost allocation to principal investigators, and more extensive collaboration and sharing of resources than might be typical in many research universities. With respect to the issue of indirect allocation to investigators, in particular, this arrangement may be more advantageous than in many other research institutions. Researchers generating full indirect also receive a discretionary allocation of around ten percent of these funds which can be used to promote additional research activity, present results and attend meetings, provide bridge support for staff, and respond to many other needs. By comparison, with state funds, this degree of flexibility is unlikely to exist.

On the other hand, having two separate entities (SDSU and the SDSURF) may complicate presenting a clear consolidated "balance sheet" to outside entities and persons. Since the standard model for research universities is one public or private entity that encompasses all activities, most accrediting bodies and other external organizations, and even individuals, find it difficult to fully comprehend the larger picture when operations and finances are divided among two separate legal entities, one a state institution and the other a nonprofit. As a result, the full impact of the GSPH's extensive teaching and research efforts are less visible. For example, on the state side the GSPH instructional, operational, and equipment budgets are perhaps $3 million per year, but the total budget including research activities approaches $25 million per year. Similarly, total employment on the state side is under 100 faculty and staff, while on the SDSURF side GSPH employment may exceed 500 individuals.

A separate research entity may not be the ideal situation but at the same time provides unique opportunities. The visibility of a separate research entity is probably greater then when submerged into a more traditional structure. Removing research administration functions from the educational side of operations, while complicating the aggregate picture, does better clarify the research effort.

SDSURF provides a mechanism to bypass state bureaucracy and to focus research efforts directly on outcome objectives. Having a highly focused mission with discrete staff and facilities avoids the more broadly based responsibilities of research administrators who serve multiple assignments and superiors. Research administration support can be provided with personnel hired exclusively for this purpose and paid at an appropriate level, independent of any direct consideration for state instructional and support salaries. Similarly, both research faculty and their research and support staff can be paid without the limitation of comparability to state employees on the instructional side. Many research staff working for faculty principal investigators are paid significantly higher salaries as an SDSURF employee then they would be paid as a state employee. And employment and other aspects of conducting the research is not as tied into the state-side bureaucracy and rules and regulations.

The development and growth of both the GSPH and the SDSURF has paralleled SDSU's own maturation. While cause and effect may not be established, the move toward creating a research based university and the expansion of graduate and professional education at SDSU certainly parallels the growth of the GSPH and the expansion of research support from the SDSURF. Creating recognition in the international educational community for academic excellence can be achieved through the expansion of research, faculty publications, and other metrics of contributing to knowledge. Attracting outstanding and well known faculty is often facilitated by successful research programming. Master's, and especially doctoral, students are attracted to institutions that provide a research setting and outstanding faculty.

A common measure of research productivity is publications in academic and professional journals, especially in peer-reviewed journals (Toutkoushian, Porter, Danielson, & Hollis, 2003). By this measure the GSPH faculty have been reasonably productive. For the last completed academic year, for example, 71% of faculty published at least two peer-reviewed publications. Total publications for core faculty during the same year was approximately 100, or an average of approximately 3.3 per faculty member. Many publications include graduate student co-authors and approximately 80% of funded faculty research has student involvement.

Another popular measure of research productivity, particularly in the health sciences, is grant activity sourced from the National Institutes of Health. A rough measure of SDSU success in this arena is reflected by computing the university's standing among all California institutional grant recipients for fiscal year 2013. Although only a rough reflection of actual allocation due to many complex factors such as multiple principal investigators and the ways in which the NIH aggregates data, SDSU still ranks in the top five percent of all institutional recipients by funding dollars (Table 2).

The past has presented many challenges, some of which will likely continue into the future. Salary scales within the CSU for faculty have historically been low in comparison to major research universities and other schools of public health. Cost of living, and especially housing, is high in San Diego. Salary supplementation opportunities through grants and contracts, facilitated by SDSURF mechanisms, as well as external consulting opportunities, provide an avenue for entrepreneurial faculty to improve their financial situation. Funding levels for supplies, physical facilities, graduate student support, and other infrastructure has always been tight as well. These factors are especially notable in comparison to many institutions with high research productivity.

Ultimately, one of the key takeaways from this experience is the question of whether an independent or freestanding research management entity is a stronger advocate and more effective approach to promoting a research agenda then an integrated one that is part of existing departments and more diffuse within the administrative structure. Many institutional research support entities are decentralized within the academic environment rather than existing as a separate research unit. The existence of a separate organizational entity has been highly effective in the situation described here and may suggest that in some other settings a structure similar to this could be beneficial. Each institution is highly unique and operates within numerous complex administrative and regulatory parameters so drawing definitive conclusions is virtually

Institution Name	Number Awards	Total Funding
University of California San Francisco	1174	$501,656,900
University of California	847	$362,004,733
Stanford University	828	$357,812,990
University of California Los Angeles	829	$341,211,533
Scripps Research Institute	335	$198,275,639
University of Southern California	385	$184,275,868
University of California Davis	439	$180,683,527
University of California Irvine	340	$126,433,097
University of California Berkeley	357	$119,785,503
California Institute of Technology	126	$59,559,501
Sanford-Burnham Medical Research Institute	123	$53,588,265
SRI International	84	$42,623,685
Salk Institute for Biological	83	$41,115,822
City of Hope/Beckman Research University	85	$36,942,940
Kaiser Foundation Research Institute	67	$36,647,504
RAND Corporation	85	$34,313,241
University of California Santa Cruz	67	$28,551,095
Cedars-Sinai Medical Center	71	$27,956,249
University of California-Lawrence Berkeley Lab	45	$27,116,291
J. David Gladstone Institutes	46	$26,575,146
San Diego State University	80	$26,533,223
Total Top 22 Institutions	6496	$2,813,662,752
Remaining 369 Institutions	1196	$520,754,615
Grant Total California	4692	$3,334,417,367

Source: Compiled from http://report.nih.gov/award/index.cfm?ot=&fy=2013&state=CA&ic=&fm=&orgid=&distr=&rfa=&om=n&pid=&view=statedetail

Table 2. National Institutes of Health Awards, Fiscal Year 2013, California Organizations

impossible. However, from a policy perspective suggesting the possibility that this approach should be considered is certainly justified.

Research organizations and universities worldwide are seeking to identify the most effective approaches to providing support to their research activities (Kirkland, 2005). Defining priority areas in which to seek extramural funding and providing a platform for efficiently managing these programs is a universal concern (Marlin, 2009). Most universities that are not totally derived from a teaching mission are seeking to assess the extent to which they should support and manage their research endeavors. Empirical evidence clearly supports the importance of appropriate managerial structure and support for these efforts, as well as the need for visible leadership and clearly defined missions (Schutzenmeister, 2010). Establishing priorities and committing to proposal development and submission has even led to the creation of a

highly specialized organization for such professionals, the National Organization of Research Development Professionals. Of course, the Society of Research Administrators International continues to provide leadership for the much larger and broader community of research management professionals. One size does not fit all, but clearly each institution must seek out the most effective and appropriate structures for achieving these research missions. That two separate entities were so effective in the instance of SDSU, and facilitated the growth of the research program, as illustrated by the GSPH, provides one effective model in one combination of circumstances.

The past 30 years of development at SDSU has at least in part been dedicated to expanding the university's research agenda and doctoral education, and achieving national visibility. Many other initiatives have focused on improving the quality of education and of life for undergraduate students. The university's new strategic plan aims to consolidate these accomplishments and to take the institution to the next level. The GSPH and the SDSURF have clearly played important roles in many university successes, and especially in graduate education, and in promoting the research environment, roles that will continue for many years in the future.

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REVIEW

Book Review

Innovation U 2.0 Reinventing University Roles in a Knowledge Economy by Tornatzky, L.G. and Rideout, E.C.

2014, Louis G. Tornatzky. 258pp.

Paul G. Waugaman
Tucson, AZ

Innovation U 2.0 is a sequel to an earlier study also called *Innovation U* published in 2002 by the Southern Growth Policies Board; with some important improvements and updates. The 2002 version was the final work in a multi-year program of policy and practice benchmarking studies involved in linking universities to the knowledge economy at national, state and community levels. Version 2.0 has brought the toolbox of good practices at exemplary institutions up to date in a systematic and thorough way.

The twelve years since the 2002 version was published have seen the good practices and policies identified become more the accepted ways of doing business than the exceptions. Business-university research collaborations, the licensing of university intellectual property, and the participation of educational institutions in new business start-ups have become more commonplace; and – as the case studies in version 2.0 illustrate – may have become more broadly distributed in the community of universities performing research.

The institutions studied in version 2.0 differ to some extent from the institutions studied in the 2002 version. Each version covers 12 institutions, but six of those included in the 2002 version are missing, six are included in both versions, and six new institutions were added in version 2.0. The authors of version 2.0 developed a well-thought—out protocol for selecting their case-study institutions that included more objective criteria than was used in the 2002 version. Although it may be fair to argue that if some exemplary institutions were left out of version 2.0; those included provide a strong sample of best practices and best practitioners for use by organizational innovators at other institutions trying to up their games.

In the introduction, the authors identify four "audiences" with a stake in universities' success at becoming and remaining active "innovation U's:"

- University leaders; CEOs, vice presidents, and governing board members,
- Change-oriented faculty members and leaders,
- Leaders in technology-based businesses, and
- Public officials who oversee expenditures of public funds for universities.

Research managers and administrators will have opportunities to relate to people in each of these classes, and should find the concepts and practices identified useful in promoting change and organizational innovation, and should therefore be interested in this work.

Elsewhere in the introduction, the authors identify the key issues upon which each of the case studies focus:

- Organizational culture and institutional goals and aspirations,
- Leadership,
- Entrepreneurship,
- Industry and community partnering, and
- Technology transfer.

The last three issues are identified as "boundary-spanning" activities which tend to operate best in the case-study universities across internal boundaries inherent in academic institutions, and across the boundaries that have separated academia from other activities. Of particular note are the approaches to encouraging entrepreneurial activity as a boundary-spanning activity. At case-study universities, entrepreneurship was not confined to business-school curricula, but flourishes as a variety of what the authors call "co-curricular" activities involving community entrepreneurial networks, interest clubs, etc. – some with long histories of success. Another domain noted is technology transfer, where the case-study institutions have tended to organize the traditional functions of a technology transfer office (reviewing inventions, seeking patent protection, and outreach and marketing IP to licensees) more closely with broader activities intended to enable the commercialization of new technologies such as incubators and accelerators and venture capital and other creative financing, with the goal of increasing the commercial value of the university's patents and other intellectual assets. The ability of an institution to enable successful disciplinary boundary-spanning research programs within the university through the creation and support of multidisciplinary problem-oriented research centers was also identified as an important trait of an innovation U.

In the concluding summary and recommendations, the authors pull together observations on each of the five issues. Predictably, the importance of leadership and culture is emphasized as it was in the 2002 version. The leadership discussion however notes the importance of a succession of institutional leaders with similar experience in boundary-spanning activity and successful achievement of linking academic and business communities. The authors also make a strong case for the importance of successful boundary spanning in being a successful innovation U.

The last section of the Summary and Recommendations includes seven recommendations for becoming a successful innovation U. Although they are presented in a straightforward and concise manner, university administrators will recognize that they are easy to recognize but difficult to attain. They remind the dedicated change agent that talking the talk is often easier than walking the walk; or even staying on the path.

One feature missing in the *Innovation U 2.0* cases are commercial success stories from these exemplary institutions. The studies concentrate on organizational arrangements and "input efforts" without specific examples of success, such as successful start-ups. Some obvious examples come to mind: Raytheon from MIT, Cree Research from N.C. State, and Google from Stanford – to name a few. Perhaps the pathway from a bench-top innovation to a public company is simply too winding and convoluted, and a large successful company is too far-removed from its beginnings to be recognizable. However a discussion of these pathways, and what the journey does to innovators and institutions might be instructive in trying to understand what an innovation U can do to facilitate or enable the journey.

Innovation U 2.0 is available in .pdf format for downloading from www.innovation-u.com.

Author's Note

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