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Celebrating 50 Years

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From the Editor's Desk

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Celebrating 50 Years of Research Administration Scholarship

The Journal of Research Administration (JRA) is turning 50 this year! Throughout the year, we will celebrate this half a century of research administration scholarship through a number of initiatives and events. First, we will be re-publishing the first issue of the journal in July 2019. Each issue published this year will feature a cover that harkens back to that of the first issue's cover. We will also be publishing special commentaries throughout the year including Ira Goodman's commentary in this issue in which he reflects on his 50 years working in the field of research administration. At the 2019 annual meeting of the Society for Research Administrators International (SRAI), we will host a number of sessions that will focus on the scholarship of research administration and we will take the opportunity during these sessions to further celebrate our golden anniversary.

In celebrating our milestone of publishing for 50 years, it is interesting to reflect on the general history of the development of research administration as a career. The story begins with the onset of research in higher education and the increased requirements for research regulatory reporting and regulations. President Roosevelt provided the first critical step in creating research guidelines and recognizing the importance of comprehensive and ongoing research (Campbell, 2010; Myers, 2008b). Many historians recognize this as the catalyst for the need for research administrators (Beasley, 2006). When professional societies began to surface in the 1950's and 1960's, SRA ("International" was added to the society's name in 2000) was founded and additional support systems grew in direct proportion to the number of new regulations created to oversee America's investment into research. Shortly after the 1980's, the demands for research accountability expanded and the explosive growth of biomedical research during the 1990's lead to an onslaught of regulatory compliance needs that faculty and non-research administrators could not fill and research administrators stepped in to fill the gap (Brandt, 1997; Campbell, 2010; Coscio, 2006; Kerwin, 1982; Myers, 2007). Finally in the 1990's through today, research administration is truly a separate and recognized profession by peers, faculty, and societies and represents a critical piece in the conduct and management of research (Brandt, 1997; Kirby, 1995). As the field of research administration grows, it becomes more important to understand and formalize the education and training of research administrators. As such, it is important for us to continue publishing our research on research administration and management.

JRA was a natural extension of the founding of SRA in 1967. The founders of the society realized that the establishment of a journal was critical to disseminating the scholarship of its members and, as such, the first issue of the journal was published in July 1969 following the second annual meeting of the society. The first article in the inaugural issue of JRA was a report summarizing activities of the research committee of SRA. This committee was charged with establishing a set of professional standards for research administrators. Not surprisingly, no data existed on what a research administrator was at that time so the committee developed and disseminated a survey to over 400 individuals that was meant to serve as the basis for understanding the characteristics of a "typical" research administrator. The survey covered topics such as identifying the job sectors employing research administrators, the scope of their work, their job titles, their genders and ages, and their education background and levels. The committee concluded from the survey results that a "typical" research administrator at the time was most likely to be a middle-aged male that had postgraduate training in business administration and worked in an academic setting on functions that dealt with such activities as budgeting, accounting, salary administration, and employee relations (D'Agostino, 1969). The results of the survey and their reporting at the society's 1969 annual meeting highlight some positives and negatives of our field in these early years. Suffice it to say that we now celebrate a much more diverse understanding of what it means to be a research administrator. In fact, we are so diverse that there likely is no single way to define a "typical" research administrator these days. Our diversity spans personal and professional demographic profiles and this diversity adds essential value to our profession.

In addition to the reporting of the aforementioned survey results, the first issue of JRA also published several other papers that speak to the heart of an emerging profession. For example, one article titled "Program of Research on the Management of Research and Development" builds the thesis that there is a need for research administrators to study and have influence on improving how research activities are managed in order to further improve how an organization manages these activities (Rubenstein, 1969). Does this sound familiar? The articles in the journal's first issue are fascinating reads when you put them into today's context. Interestingly, we are still thinking about and developing some of the ideas presented in these early articles. Over the years, since publishing the first issue of the journal, we have certainly evolved as a profession and we have sharpened our scholarship in the field, but we continue to face some of the same opportunities and challenges as our predecessors. We encourage you to read the first issue of JRA when we re-publish it in July and reflect for yourself on the past history of the society, the journal, and our field.

Looking into the future, research administrators will need to continue to enhance our current practices while, at the same time, dealing with emerging and expanding challenges, including but not limited to those relating to commercialization, partnerships with business and industry, intellectual property, interdisciplinary and multi-site efforts, and increasingly diverse foundation and for-profit sponsored program support. These will require the development of new models and approaches to sponsored support agreements that address such concerns as ownership of intellectual property and raw data, publication permissions, and indirect costs or alternative models for recovery of such costs. Additionally, the increasing levels of multi-site and transdisciplinary groups jointly pursuing funding will require the ability to rapidly and effectively

develop grants and contract agreements that are able to address the nuances of apportionment of funds and recognition for leadership of various aspects of funded projects, as well as the differential processes and policies across participating institutions. Of course, as international collaborations with academic and for-profit entities continue to grow these challenges will be magnified, with the ever more complex issues confronting transnational intellectual property sharing.

In addition to the content issues confronting research administration, we will also need to develop and implement increasingly complex and flexible electronic research systems that can be integrated with other systems of the organization, including both financial and compliance systems. These systems will need to also be ones that are careful to attend to decreasing the administrative burdens on investigator teams while at the same time providing for transparency, accountability and monitoring of projects.

In closing, SRAI, JRA, and all of us as research administrators have much to be proud of as we look back on 50 years of research administration scholarship. We have much to owe to our predecessors, particularly our colleagues who have held leadership positions in the society and journal. We now stand on the shoulders of the past editors, editorial board members, and society staff that made each issue of JRA possible. We are indebted to everyone that has dedicated significant time and effort to the development of this field and the journal. We can also look forward to the future with much confidence as new leaders emerge and as the field continues to swiftly mature and advance into new areas.

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Remembering 50 Years In Research Administration

Ira S. Goodman
UC San Diego Moores Cancer Center

Introduction

2018 marks my golden anniversary in research administration. I started at New York University on July 15, 1968. Fifty years is a long time to spend in one profession. For me, it was a perfect match. I embraced academic research administration and witnessed transformative changes, a sampling of which is described below. This retrospective reflects my views on how research administration has evolved over a half century through regulations, technology and professional practice.

Over the course of my career I have held positions as a department administrator (twice), director of a grants office and administrator of NCI designated comprehensive cancer centers at two institutions—New York University and University of California, San Diego. Accordingly, I have witnessed the changes from the department, campus and research center levels.

The Regulatory Landscape

Fifty years ago research administration was in its infancy. The NIH budget was just under $1 billion as compared to the 2018 budget of $37 billion (Kaiser, 2018). There were 9 institutes; now there are 20 (not counting centers), and the flow of federal regulations was just beginning. The guiding principles I am most familiar with cover costs, property and protection of research subjects. The original OMB Circular A-21 was issued in 1958, and applied to research and development grants between the federal government and educational institutions. A-21 defined direct and indirect costs, and it set standards for accountability, documentation, and consistency. Institutions receiving less than $250,000 in awards were permitted to use a simplified method (short form) to calculate and allocate indirect costs. Over the 1960's revisions of A-21 clarified and refined methods used in identifying, classifying, and distributing indirect costs, modification of effort-reporting requirements and in 1969 the federal funding limit was raised to $1 million for universities that wished to use the simplified method (short form). Principles and guidelines to be used in determining costs for training and educational service agreements were established. In 2015 OMB Circular A-21 was revamped in CFR Part 200 as Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards. A-21 and its successor remain the ultimate source for interpreting and implementing federal regulations on research grant allowable costs relating to universities. The Public Health Service Grants Policy Statement (HHS, 2007) summarizes and categorizes the cost principles and should be a required reference resource for every research administrator.

We in the Office of Grants Administration and Institutional Studies, which was NYU Medical Center's central grants office, were charged with the responsibility of monitoring the changes in federal cost principles and disseminating them to the accounting department and principal investigators. Regulations involving intellectual property and physical property also had a

major impact on research and research administrators. The 1980 Bayh–Dole Act or Patent and Trademark Law Amendments Act changed the ownership of inventions made with federal funding. Previously, inventors had to assign inventions they made using federal funds to the federal government. Bayh–Dole permits a university, small business, or non-profit institution to elect to pursue ownership of an invention independent of the government. Consequently, technology transfer offices rapidly sprung up at universities to capitalize on all inventions with commercial potential, including those made through federal funding. The Grants Office before 1980 was a clearinghouse for reporting inventions to the federal agencies; subsequently, inventors began dealing directly with the institutional technology transfer office and legal counsel to distill their inventions into patents.

In the 1990's the federal government loosened its regulations on title to equipment purchased under grants and contracts. Equipment is defined as property having a useful life of more than a year and an acquisition cost of more than $5,000 per unit. Where previously the government retained title to equipment purchased under its funding, this change in the regulations (45 CFR Part 74.34) allowed both not-for-profit and for-profit grantees to retain title to equipment purchased with federal funds. With institutions taking ownership of grant-supported equipment, research administrators assumed greater responsibility for the management, allocation and disposition of equipment once the funding grant terminated.

Research involving human subjects was becoming regulated beginning in the 1970's. Regulations governing the oversight functions of the FDA date back to the early 1900's, making it one of the oldest consumer regulatory agencies in the federal government. The Food and Drug Act was created in 1906 and was replaced by the Federal Food, Drug and Cosmetic Act of 1938. The Act was revised many times; in 1976 it was amended to provide for the safety and effectiveness of medical devices intended for human use and other purposes. The FDA regulations, 21 CFR 11, have been constantly evolving, including the banning of carcinogens in food products, oversight of medical devices and implants, more stringent requirements for new drug applications and investigational new drug approvals.

The landmark National Research Act of 1974 codified in 45 CFR 46 the requirements for the establishment of IRBs and IRB approval of human subjects research supported by Public Health Service agencies. The Act created the NIH Office for Protection from Research Risks which negotiated General Assurance Agreements with institutions receiving NIH funds for research involving human subjects; institutions henceforth would create and maintain Institutional Review Boards to approve and monitor human subjects research. Over time, the regulations would be expanded to provide for extra protections for children, prisoners, pregnant women and fetuses. They would require that institutions apply the same ethical standards to all human subjects research. The Federal Policy for the Protection of Human Subjects or the "Common Rule" was published in 1991 and codified in separate regulations by 15 federal departments and agencies, virtually all of the agencies supporting human subjects research. As a grants office manager, I was on the front lines of implementing and overseeing the protection of human subjects. In 1975 I had the honor of meeting with Drs. Charles McCarthy and Charles McKay, the directors of the Office for Protection from Research Risks, as they were drafting the original regulations. They were seeking institutional advice from around the country on striking a balance

between fully protecting human subjects and not overly burdening institutions. The Grants Office was responsible for transcribing 45 CFR 46 into institutional policies and procedures, creating and supporting the Institutional Review Board and managing its proceedings. It was groundbreaking work, but it was also very exciting to create a new compliance system that would stand up to FDA audit. I managed and also served on the IRB (ex officio) for many years. The FDA is the responsible federal agency for overseeing institutional human subjects compliance. I also participated in a number of FDA audits of our IRB. Fortunately, no major exceptions were reported.

The Laboratory Animal Welfare Act (P.L. 89-544) was enacted in 1966. It is the only federal law that regulates the treatment of animals in research and exhibition. Other laws, policies, and guidelines may include additional species coverage or specifications for animal care and use, but all refer to the Animal Welfare Act (AWA) as the minimally acceptable standard for animal treatment and care. The AWA created the requirement for institutional surveillance of animal care through Institutional Animal Care and Use Committees (IACUC). The AWA required that federally funded research involving laboratory animals receive IACUC approval prior to award. The Grants Office also managed the IACUC with the help of the animal care program. We collected the animal protocols, distributed them to the IACUC and managed the meetings. I was a member of the IACUC and became familiar with the AWA, helping to draft institutional compliance policies. It wasn't unusual in the early days for research administrators in the Grants Office to wear many hats and become the institutional experts in interpreting federal rules pertaining to research grants.

Institutional Biosafety Committees (IBCs) were created to review research involving gene splicing or recombinant DNA and potential cloning. The original NIH Guidelines for Recombinant DNA Research were issued in 1976. They assigned each type of recombinant DNA experiment a specific level of "physical containment" and of "biological containment". Responsibility for overseeing the application of the guidelines belongs to the NIH Recombinant DNA Advisory Committee (RAC)—composed of scientists and laymen, including non-voting representatives from many federal agencies—and local institutional biosafety committees at each university where recombinant DNA research is conducted. The NIH guidelines were subsequently adopted by other federal agencies, but congressional proposals aimed at extending the guidelines to private industry did not result in national legislation. The NIH guidelines underwent a major revision in 1978 and have been revised a number of times since then. The institutional review and regulation of biomedical research, specifically human subjects, animals and recombinant DNA, would establish a critical role for research administrators. Similar to the institutional response to the National Research Act and the Animal Welfare Act, the Grants Office managed the IBC. Looking back, it is quite startling to acknowledge the central and critical role the Grants Office and its leadership played in shaping the spectrum of research administration policies. It is also somewhat remarkable how much responsibility was concentrated in a relatively small work force.

The study of stem cells introduced another road bump in the regulation of biomedical research. Stem cells are a class of undifferentiated cells that are able to differentiate into specialized cell types. Commonly, stem cells come from two main sources: embryos formed during the blastocyst phase of embryological development (embryonic stem cells) and adult tissue (adult stem cells).

Stem cells have been used in medicine since the 1950's when bone marrow transplants were first used to treat leukemia. Congressional involvement in stem cell policy started as early as 1974. Prior to 2009, federal funding was limited to non-embryonic stem cell research and embryonic stem cell research based upon embryonic stem cell lines in existence prior to August 9, 2001. A 2009 Executive Order allowed for NIH to support and conduct human stem cell research, including human embryonic stem cell (hESC) research, to the extent permitted by law. In certain cases restrictions on federal funding for research involving new lines of human embryonic stem cells were lifted. Federal funding by the NIH continues to prohibit stem cell research for the creation of a human embryo for research purposes, or research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero. A number of states, including California, enacted their own regulations and funding mechanisms for stem cell research.

The most recent regulatory hurdle in clinical research is the change in federal reimbursement for patients on clinical trials. In 2003, National Coverage Determinations were expanded to include the reasonable and customary costs of treatment for patients participating in therapeutic clinical trials. This was a major victory for clinical trial patients and institutions providing such care. However, this has led to questionable charges and potential double billing to sponsors and carriers, which has required institutions to establish an intensive internal review system for bills to patients on clinical trials. This process, known as a coverage analysis, affects virtually all health providers treating patients on clinical trials whereby they must screen their invoices to public and private insurance carriers to avoid duplicate billing. This responsibility is shared between the health system and the clinical research administrators. The institutional response to the challenge of submitting reimbursement claims for patients participating in clinical trials was a joint responsibility of the clinical trials offices coordinating the research and the hospital's revenue cycle office. In 2012, while at UC San Diego, I joined a team composed of hospital finance, clinical research and computer programming administrators called the Clinical Research Billing Steering Committee. The committee sought to build a network that would integrate the clinical trials management system (CTMS) with the electronic medical record (eMS) for screening and separating patient visits into billable and non-billable events. Over time this system has allowed the institution to bill with far greater confidence and accuracy, reducing the bill holds that were hindering cash flow.

In summary, I witnessed the introduction of a regulatory framework of institutional review and monitoring of biomedical research that exists with growing scrutiny to this day. This challenged the research administration community to invest resources in faculty level committees, policies, procedures and staff time to comply with federal regulations. To support this effort, research administrators began networking to facilitate the creation of an institutional structure of professional administrators, compliance offices and formal policies to implement the regulations. It was in this burgeoning regulatory environment that organizations such as SRA, NCURA, NACUBO and others had their roots.

Technology Transforms Research Administration

The upsurge in office-centric technology since the 1960's affected research administration as much as the increasing regulatory environment, only in the opposite direction. Where the burden of compliance significantly increased the time, effort and expense of research administration, rapidly evolving technology reduced the time, resources and costs of both pre- and post-award grant management. That is not to say less people or funding were needed to respond to the external and internal growth of research required services; only that the work involved became more efficient as advanced electronic tools became available.

Imagine the workplace without high speed calculators, desktop computers, word processors, fax machines, email, and smart phones. I don't have to imagine it—I was there. But just as we view progress of any sort over time, we saw the workplace as constantly improving, with every innovation making our jobs a little easier. Carbon paper—yes, carbon paper—was a tremendous tool in grant application assembly. Multiple copies of the application could be typed (and corrected with great effort) at once. White out™ (remember?) allowed for correcting typing errors, even in multiple colors. Thermal fax machines—although painfully slow and hot to the touch—sent messages over telephone lines to grant officials beginning in the 1960's. Xerox™ machines were a huge step forward, making the copying of a grant application an automated rather than a carbon copy process. The word processing machine—the Wang 1200 WPS—was introduced in June 1976 and was an instant success, as was its successor, the 1977 Wang OIS (Office Information System). These products were true technological breakthroughs. I acquired one in 1980, replacing my IBM Selectric. It was much more than a replacement; it was revolutionary. IBM and Microsoft formed a partnership in 1980 to create an operating system known as OS/2 for the early IBM computer. Apple meanwhile came out with its own version of the computer in 1976. As we know, scientists gravitated to Apple products, and administrators favored PCs, led by IBM, making the proofing and editing of grant proposals by principal investigators and administrative staff quite vexing. From my perspective PCs seemed to be easier to use and had more office type features. The internet was created in the 1980's which led to a technological transformation in communication. The telephone gave way to the internet, as did much of the postal service. Verbal communication morphed into digital contact. No longer would we place a telephone call to a principal investigator to no avail; waiting a day or longer for correspondence with a grating agency to be read. NIH applications, for the longest time submitted in 6 copies, via the US Postal Service or courier (how many times have you flown to DC and taken local transportation to NIH in Bethesda to deliver a grant application to Room 240 at the Division of Research Grants?), could be submitted via a computer terminal. All of a sudden (well, it wasn't really all of a sudden), grant reviews and grant award notices were transmitted electronically. Eventually, internal grant and regulatory reviews were processed electronically, saving significant time and money in duplicating and staff costs. It's breathtaking to consider the lightning speed (relatively speaking) at which research administration has been transformed by technology. I almost feel sorry for research administrators who missed the transition from print to digital, from grant application submission by postal service or courier to instantaneous computer submission, from telephone tag to email messaging.

Research Administration Hits its Stride as a Profession

When I started, research administrators per se didn't exist. We had position titles of department administrator or coordinator, program manager, executive/administrative assistant, grant and contract specialist, fund manager, grant accountant, grant analyst and the like. Of course, many of these titles exist today. There was no Dean/VP for Research. The Grants Office was the administrative center of all things research. Over the years, to comply with increasing regulations, but also in response to significant increases in the federal budget, research administration became a highly specialized profession with on-site and multiple external sources of training and education. A college degree was not required for a management position; now certain jobs require advanced degrees. There are certificate programs and graduate degrees in research administration. Indeed, the profession of research administration has become so broad and complex that it contains subspecialties of compliance, research risks, ethics, sponsored projects pre- and post-award administration, clinical research management, and research finance, to name a few. In the past, an individual would be internally promoted into research management; today, research administration has become a sought after profession starting early in the career selection process.

Business dress has also been updated. When I started, suits and ties were the male uniform de rigueur. Today, a somewhat more casual dress is considered quite acceptable; ties are optional, as are jackets. However, jeans still are not widely accepted in the research administration office workplace (which is fine by me). Networking has been made significantly easier through the growth of professional organizations, the internet and social media. Research administration career advancement was so much more limited back then as compared to the 21st century. However, it must be noted that the Society of Research Administrators (in its globally restructured form as the Society of Research Administrators International) celebrated its 50th anniversary in 2017 and the Journal of Research Administration's 50th anniversary is 2019. We grew up together.

So how much has research administration changed in 50 years? From my perspective, the greatest change has been in how it has matured. It now attracts and requires individuals from a wide spectrum of professional backgrounds including science, accounting, engineering, ethics, law, finance, and non-profit management. It now requires so much more knowledge and expertise. It has transformed from paper to digital communication, greatly facilitating the growth and speed of business. Research administration has developed into an essential leadership role at universities and not-for-profits. On the other hand, it has not changed in the challenges to provide specialized service to investigators and institutions alike, to respectfully respond to granting agency requirements, and to conduct our business by applying the most stringent means to meet all legal, ethical and public expectations. My deep respect to those who have flourished in this environment and my best wishes to all whose careers will further advance our profession and the products of the research we support.

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Developing Language to Communicate Privacy and Confidentiality Protections to Potential Clinical Trial Subjects: Meshing Requirements under Six Applicable Regulations, Laws, Guidelines and Funding Policies

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Abstract: *Clinical trials must address a number of laws, regulations, and other sources of requirements when communicating privacy and confidentiality protections to potential participants. This article outlines relevant requirements from Common Rule regulations, Food and Drug Administration regulations, Health Insurance Portability and Accountability Act regulations, International Council for Harmonisation guidelines, the Confidentiality of Substance Use Disorder Patient Records statute, and Certificates of Confidentiality provisions under the 21st Century Cures Act. A consent form template is presented as one example of language that incorporates all of these requirements in an integrated manner that addresses some of the tensions among the various requirements.*

Keywords: *Informed Consent, Confidentiality, Privacy, Common Rule, Certificate of Confidentiality, HIPAA*

Introduction

An effective process for satisfying the ethical obligation to obtain informed consent for participation in clinical research requires that potential subjects be informed about the consequences of agreeing to be part of the research (Lentz, Kennett, Perlmutter, & Forrest, 2016). Consent processes and forms must include a description of privacy and confidentiality protections and need to disclose the possibility that private information collected for the research

will become known outside the research context. The confidentiality section of consent forms generally must adhere to requirements from at least six different sources: from the Federal Policy for the Protection of Human Subjects ("Common Rule" [HHS, 2005; 2017]; including changes with a general compliance date of January 21, 2019), from the Food and Drug Administration ("FDA") regulations for the Protection of Human Subjects (FDA, 1981), from the International Council for Harmonisation ("ICH" [ICH, 1996, 2016]), from regulations under the Health Insurance Portability and Accountability Act ("HIPAA" [HHS 2000a, 2000b]), from regulations concerning Confidentiality of Substance Use Disorder Patient Records ("Part 2" [HHS, 2018a]), and from the 21st Century Cures Act ("Cures Act" [Cures Act, 2016]) and associated National Institutes of Health ("NIH") funding policy on Certificates of Confidentiality (NIH, 2017a). In addition, many states have laws and regulations concerning the privacy or confidentiality of specific types of health information (Mello, Adler-Milstein, Ding, & Savage, 2018).

The precipitating event for addressing the harmonization of the confidentiality requirements was NIH's implementation of the Cures Act requirement to provide Certificates of Confidentiality for all NIH funded research (NIH, 2017b). The language suggested by NIH for consent forms (2017c) has a Flesch-Kincaid Grade Level score of 19 (post-graduate level; Wolf & Beskow, 2018), and is presented in isolation, without guidance or a model for integration with other privacy or confidentiality requirements.

At Boston Medical Center ("BMC") and Boston University ("BU") Medical Campus, which share a Human Research Protection Program ("HRPP"), our previous consent forms addressed each requirement in a separate section. In considering how to incorporate the Cures Act language much more frequently, some examples were found of templates that combine the Common Rule and Cures Act language (NIH, 2018) or the Common Rule and HIPAA language (Boston Children's Hospital IRB, 2018), or that simplify the Cures Act language (Wolf & Beskow, 2018). However, none that we found integrated the presentation of confidentiality and privacy requirements in a manner that reduced redundancy and addressed inconsistencies among the requirements.

An overall requirement for consent forms is that they are "in language understandable to the subject or legally authorized representative" (HHS, 2005, §46.116; HHS, 2018b, §46.116[a][3]), "written in plain language" (HHS, 2000b, §164.508[c][3]), "and organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates the prospective subject's or legally authorized representative's understanding of the reasons why one might or might not want to participate" (HHS, 2018b, §46.116[a][5][ii]). We felt that simply adding Certificate of Confidentiality language to our existing template would not be consistent with these requirements. This article describes the revision of our consent template to mesh the applicable requirements into an integrated explanation of how subjects' identifiable information will be handled.

Methods

The process of revising the existing consent form privacy and confidentiality language to incorporate all requirements started with the realization that merely adding NIH's suggested Certificate of Confidentiality language (NIH, 2017c), or using a simplified version (we considered using the same simplified language as University of Nevada, Reno; Wolf & Beskow, 2018, p. 355), would not meet our goal of being understandable to subjects. Three of the authors of this article (FKE, PAB, LOH) were the main individuals involved in the development of the template, with consultation during the process by ECF and review of the completed template by SN. The development process also involved review by our HRPP Advisory Committee, and the final version was approved by our Institutional Review Board ("IRB") Executive Board.

In developing the integrated template, we identified all pertinent requirements, including both the definitions of what made information identifiable, and the elements, information, and statements that should be included in the consent form. Table 1 lists the definitions of what makes information identifiable from the six different sources, ranging from what is arguably the narrowest definition, in the Common Rule, to the broadest definition, in the Cures Act. Table 2 lists the relevant requirements for the content of consent forms from these six sources.

Revisions to the existing consent template required numerous drafts, trying out different simplifications and rearrangements, with particular attention to removing redundancies and reconciling potential contradictions among the requirements (the Discussion section addresses the four major issues we confronted). Each draft was checked for reading level (using the Flesch-Kincaid grade level scoring tool that is embedded in Microsoft Word) and for compliance with the requirements in Tables 1 and 2, and assessed for overall readability and understandability in the judgement of the authors and additional reviewers. Our consent form template is structured to be useable in a variety of circumstances depending on the details of a particular study (whether biospecimens are obtained, whether information will be placed in the subject's medical record, whether information subject to mandated reporting is gathered, etc.). Extending this structure to incorporate the variables needed for the discussion of privacy and confidentiality was an additional challenge of this project, which was addressed by grouping variable sections and making extensive use of parenthetical directions to users of the template.

Table 1. Definitions of Identifiability

Source	Definition
Common Rule	Identifiable information means that the identity of the subject is or may readily be ascertained by the investigator (HHS, 2005, §46.102[f]; HHS, 2017, §46.102[e][5]). This definition will be reexamined within one year of the effective date of the revised Common Rule and at least every 4 years thereafter (HHS, 2018b, §46.102[e][7][i]).
FDA	Identifiability is not defined in the human subjects protections regulations.
HIPAA	Identifiable information is information that identifies the individual or with respect to which there is a reasonable basis to believe the information can be used to identify the individual (HHS, 2000b, §160.103).
ICH	Identifiability is not defined in the human subjects protections guidelines.
Part 2	Identifying information means the name, address, social security number, fingerprints, photograph, or similar information by which the identity of a patient can be determined with reasonable accuracy either directly or by reference to other information (HHS, 2018a, §2.11).
Cures Act	Identifiable information is defined as information for which there is at least a very small risk, as determined by current scientific practices or statistical methods, that some combination of the information, a request for the information, and other available data sources could be used to deduce the identity of an individual. All identifiable research information is considered identifiable sensitive information (Cures Act, 2016, HHS, 1944, §241[d][4]).

Table 2. Consent Form Requirements

Source	**Requirements** (numbered for reference in the Results section)	
Common Rule	CR-(1)	Informed consent must include a statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained (HHS, 2005, §46.116[a][5]; HHS, 2018b, §46.116[b][5]).
	CR-(2)	Informed consent must include a statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility (HHS, 2018b, §46.116[b][9][i]).
FDA	FDA-(1)	Informed consent must include a statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained and that notes the possibility that the Food and Drug Administration may inspect the records (FDA, 1981, §50.25[a][5]).
	FDA-(2)	For applicable clinical trials, as defined in 42 U.S.C. 282(j)(1)(A), the following statement must be provided to each clinical trial subject in informed consent documents and processes: "A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time" (FDA, 1981, §50.25[c]).
HIPAA*	HIP-(1)	Authorizations must include a description of the PHI to be used or disclosed that identifies the information in a specific and meaningful fashion (HHS, 2000b, §164.508[c][1][i]).
	HIP-(2)	Authorizations must include the name or other specific identification of the person(s), or class of persons, who will make the requested use or disclosure (HHS, 2000b, §164.508[c][1][ii]).
	HIP-(3)	Authorizations must include the name or other specific identification of the person(s), or class of persons, to whom the Covered Entity may make the requested use or disclosure (HHS, 2000b, §164.508[c][1][iii]).

	HIP-(4)	Authorizations must include a description of each purpose of the requested use or disclosure (HHS, 2000b, §164.508[c][1][iv]).
	HIP-(5)	Authorizations must include an expiration date or an expiration event that relates to the individual or the purpose of the use or disclosure. The statement "end of the research study," "none," or similar language is sufficient if the authorization is for a use or disclosure of PHI for research (HHS, 2000b, §164.508[c][1][v]).
	HIP-(6)	Authorizations must include the signature of the individual and date. If the authorization is signed by a personal representative of the individual, a description of such representative's authority to act for the individual must also be provided (HHS, 2000b, §164.508[c][1][vi]).
	HIP-(7)	Authorizations must include a statement concerning the individual's right to revoke the authorization in writing and the exceptions to the right of revocation, including in particular the ability of the researchers to continue to use and disclose as necessary to preserve the integrity of the research and for institutional or governmental oversight (HHS, 2000b, §164.508[c][2][i]).
	HIP-(8)	Authorizations must include a statement concerning whether providing the authorization is a condition for treatment, payment, enrollment, or eligibility for benefits. Research-related treatment may be conditioned on providing the authorization; however, the statement must inform the individual about the consequences of not signing the authorization (HHS, 2000b, §164.508[c][2][ii]; §164.508[b][4][i]).
	HIP-(9)	Authorizations must include a statement concerning the potential for information disclosed pursuant to the authorization to be re-disclosed by the recipient and no longer be protected by HIPAA (HHS, 2000b, §164.508[c][2][iii]).
ICH	ICH-(1)	The informed consent should include explanations that the monitor(s), the auditor(s), the IRB, and the regulatory authority(ies) will be granted direct access to the subject's original medical records for verification of clinical trial procedures and/or data, without violating the confidentiality of the subject, to the extent permitted by the applicable laws and regulations and that, by signing a written informed consent form, the subject or the subject's legally acceptable representative is authorizing such access (ICH, 2016, 4.8.10[n]).

	ICH-(2)	The informed consent should include explanations that records identifying the subject will be kept confidential and, to the extent permitted by the applicable laws and/or regulations, will not be made publicly available. If the results of the trial are published, the subject's identity will remain confidential (ICH, 2016, 4.8.10[o]).
Part 2	Pt2-(1)	Consent for disclosures of identifiable information about substance use outside the Part 2 program must include essentially the same elements required for a HIPAA authorization. The consent requirement varies based on whether the recipient does or does not have a treating provider relationship with the patient (HHS, 2018a, §2.31).
	Pt2-(2)	Information necessary for the investigation of crimes and child abuse and neglect may be disclosed without consent (HHS, 2018a, §2.22[b]).
	Pt2-(3)	Identifiable Part 2 information may be used for research if confidentiality protections are adequate, including uses approved by an IRB and uses where the information is reported in such a way that patients cannot be re-identified (HHS, 2018a, §2.52).
Cures Act**	CA-(1)	With four exceptions (see CA-(2) below), any person or institution to whom a Certificate of Confidentiality is issued is prohibited from disclosing or providing to any other person not connected with the research a subject's name or any information, document, or biospecimen that contains identifiable, sensitive information and that was created or compiled for purposes of the research (HHS, 1944, §241[d][1][B]).
	CA-(2)	The four exceptions are for a disclosure or use that is:
		CA-(2)(a) Required by Federal, State, or local laws, with an exclusion to this exception for legal proceedings (see CA-(3) below) (HHS, 1944, §241[d][1][C][i]).
		CA-(2)(b) Necessary for the medical treatment of the individual to whom the information, document, or biospecimen pertains and made with the consent of such individual (HHS, 1944, §241[d][1][C][ii]).
		CA-(2)(c) Made with the consent of the individual to whom the information, document, or biospecimen pertains (HHS, 1944, §241[d][1][C][iii])
		CA-(2)(d) Made for the purposes of other scientific research that is in compliance with applicable Federal regulations governing the protection of human subjects in research (HHS, 1944, §241[d][1][C][iv]).

CA-(3) The exclusion to exception CA-(2)(a) is that any person or institution to whom a certificate is issued is prohibited, except with the consent of the individual, from disclosing or providing the name or any information, document, or biospecimen that contains identifiable, sensitive information and that was created or compiled for purposes of the research, in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding. Identifiable, sensitive information protected under a Certificate of Confidentiality, and all copies thereof, are immune from the legal process, and may not, without the consent of the individual to whom the information pertains, be admissible as evidence or used for any purpose in any action, suit, or other judicial, legislative, or administrative proceeding (HHS, 1944, §241[d][1][D]).

CA-(4) Identifiable, sensitive information collected by a person or institution to whom a Certificate of Confidentiality has been issued, and all copies thereof, are subject to the protections afforded by the Certificate of Confidentiality in perpetuity (HHS, 1944, §241[d][1][F]).

CA-(5) Having a certificate does not limit the access of an individual who is a subject of research to information about himself or herself collected during such individual's participation in the research (HHS, 1944, §241[d][3]).

*HIPAA requirements refer to authorization to use and disclose Protected Health Information ("PHI") by a Covered Entity, with elements and statements that may be incorporated into research consent forms (HHS, 2000b, §164.508[b][3][i]).

**The Cures Act requirements for confidentiality (Cures Act, 2016) have been implemented by NIH through automatic issuance of Certificates of Confidentiality to all NIH-funded research (NIH, 2017a). In addition, Certificates of Confidentiality may be issued by other funding agencies within the Department of Health and Human Services for research that these agencies support, as well as by NIH for other health-related research that uses identifiable, sensitive information (NIH, 2017a; Wolf & Beskow, 2018).

Results

The consent form confidentiality and HIPAA sections that we developed are presented in Tables 3-5. The example used is for an NIH-funded clinical trial that obtains identifiable information and biospecimens, that will place study information in the subjects' medical records, that follows ICH-GCP guidelines, that plans to share information with other researchers, that gathers information that must be reported to external public health or public safety authorities, that may obtain consent from a legally authorized representative, and that will use and disclose PHI, including substance use disorder records from a federally-assisted program. Underlined, italicized words indicate study-specific details to be completed by the investigator. Bracketed sentences indicate directions to the person preparing the consent form about the inclusion of specific items. The full templates are available from the BMC and BU Medical Campus IRB (2018) website: http://www.bumc.bu.edu/irb/inspir-ii/irb-templates/.

Table 3. Consent Form Template Confidentiality Section

Paragraph	Requirements	Comments
We must use information that shows your identity to do this research. Information already collected about you will remain in the study record even if you later withdraw.	CR-(1) FDA-(1) ICH-(2) HIP-(7)	The first sentence introduces the Confidentiality section as the discussion of the use of identifiable information. The second sentence is always true for FDA-regulated research. For other research, if an investigator would like to give subjects the opportunity to withdraw already-collected data, the investigator may edit this second sentence.
We will store your information in ways we think are secure. We will store biological samples taken from your body (such as urine, blood, or tissue) *description of storage methods*. We will store paper files in locked filing cabinets. We will store electronic files in computer systems with password protection and encryption. However, we cannot guarantee complete confidentiality.	CR-(1) ICH-(2)	This paragraph describes the protections against **unintentional** disclosure outside the research context, with the caveat that confidentiality is not guaranteed. The remainder of the confidentiality and HIPAA discussion addresses **intentional** disclosures.
This study is covered by a Certificate of Confidentiality (CoC) from the National Institutes of Health. All studies funded by the National Institutes of Health that involve identifiable information or biological samples are covered by a CoC.	CA-(1) CA-(2)(b) CA-(3) CA-(4) CA-(5)	This paragraph, complying with several of the requirements of the Cures Act, is placed early in the confidentiality section so the phrase "except as we describe below" can be used to communicate the exceptions to the general prohibition under the Cures Act against the disclosure of research information. Note that the subsequent paragraphs are included in the consent form even if there is no Certificate of Confidentiality.

The CoC provides how we can share research information or biological samples. Because we have a CoC, we cannot give out research information or biological samples that may identify you to anyone that is not involved in the research except as we describe below. Even if someone tries to get your information or biological samples in connection with a legal proceeding, we cannot give it to them. The CoC does not prevent you from sharing your own research information. We will record information from this study in your medical record, such as information related to your medical care. Please ask us if you have any questions about what information will be included in your medical records. You should know that once information has been put into your medical records, it is not covered by the CoC. However, information in your medical records is protected in other ways.	The sentences describing the Certificate of Confidentiality protections are written to apply whether or not the study gathers information that the subject might consider incriminating (see Results and Discussion). The last four sentences in this paragraph were added to convey that the Certificate of Confidentiality does not prevent research information from being placed in the subject's medical record (the first of these four sentences functions as the consent needed under the Certificate of Confidentiality—but not under HIPAA—to disclose information for treatment purposes) and to point out that although information in the medical record is not covered by the Certificate of Confidentiality, it is protected in other ways. These additional ways, such as HIPAA, Part 2 regulations, and state privacy laws, are referenced in general but not spelled out in the consent form for the sake of brevity.

If you agree to be in the study and sign this form, we will share information and biological samples that may show your identity with the following groups of people: • People who do the research or help oversee the research, including safety monitoring. • People from Federal and state agencies who audit or review the research, as required by law. Such agencies may include the U.S. Department of Health and Human Services, the Food and Drug Administration, the National Institutes of Health, and the Massachusetts Department of Public Health. • People who see your medical records. • People who will get information and biological samples from us: *name(s) and affiliation(s)*. These people are expected to protect your information and biological samples in the same way we protect it. • Any people who you give us separate permission to share your information.	ICH-(1) FDA-(1) Pt2-(3) CA-(2)(b) CA-(2)(c) CA-(2)(d) CA-(4)	This paragraph lists instances where identifiable information will be disclosed outside the research team, in conformance with the Cures Act requirement for the subject to consent to such disclosures. Because this discussion would be of interest to all potential subjects, it is also required for studies without a Certificate of Confidentiality. It gives specific examples of disclosures required by law (safety monitoring, auditing). The statement about FDA (and other regulatory bodies) being able to see the records was moved out of the HIPAA section in an earlier version of the template to avoid the implication that authorization was required for FDA to see identifiable data. The introductory phrase "If you agree to be in the study and sign this form" and the last bullet "Any people who you give us separate permission to share your information" communicate the idea that disclosures are allowed if made with the subject's consent. Calling out the fact that people who see the subjects' medical records will have access to the research information helps the subjects understand that they are providing consent for the research information to be disclosed to treating providers and others with medical record access, as required under the Cures Act. The investigator is expected to list anyone else in the fourth bullet who will get identifiable information. This is of interest to all potential subjects, and in addition, if substance abuse information is obtained, will disclose that identifiable information may be used for research purposes under PT2-(3). The Cures Act requirement CA-(4) that the protections apply to "all copies" of the information is communicated by the statement "These

		people are expected to protect your information and biological samples in the same way we protect it," which tempers a later sentence in the HIPAA section required by HIP-(9) about HIPAA not applying to PHI after it is released.
You should know that we are required to report information about: *list of information requiring mandatory reporting such as child abuse or neglect; elder abuse; specific reportable diseases; harm to self or others.*	CR-(1) Pt2-(2) CA-(2)(a)	This paragraph is included if any of the information that is gathered is subject to mandatory reporting under state or local laws. This is another specific example of the exception CA-(2)(a) under the Cures Act for disclosures required by law. It is placed in a separate paragraph to emphasize this potential exception to confidentiality, because it could be critical to a prospective subject's decision about whether or not to participate.
We will share research data where we have removed anything that we think would show your identity. There still may be a small chance that someone could figure out that the information is about you. Such sharing includes: • Publishing results in a medical book or journal. • Adding results to a Federal government database. • Using research data in future studies, done by us or by other scientists. • Using biological samples in future studies, done by us or by other scientists.	CR-(1) CR-(2) ICH-(2) Pt2-(3) CA-(2)(c)	This paragraph is written to take into account the varying interpretations of "identifiability." The first bullet, to reassure subjects that the reporting of the research will not identify them, complies with the ICH-(2) as well as the Common Rule requirement CR-(1) to describe confidentiality. Similarly, the second bullet covers any future sharing of de-identified data, such as required under Federal grant or journal publication requirements. The third and fourth bullets comply with the Common Rule requirement CR-(2) to tell subjects that their de-identified data and biospecimens may be shared in the future. The second sentence in the introductory part "There still may be a small chance that someone could figure out that the information is about you" was added because under the Cures Act (2016), information is considered identifiable if there is "at least a very small risk" of deducing the identity of the individual and therefore under requirement CA-(2)(c), the subject who signs the consent form is

		giving consent for these disclosures. The Part 2 regulations allow potentially identifiable data to be used without consent for research purposes, but it is appropriate to inform subjects that this might be a possibility.
A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.	FDA-(2)	This paragraph is required verbatim by the FDA regulations (1981, §50.25[c]). There is no option to reword to make the connection with the previous paragraphs clearer.

Table 4. Consent Form Template Use and Disclosure of Your Health Information (HIPAA) Section

Paragraph	Requirements	Comments
The research team has to use and share your health information to do this study, including information that may identify you. By agreeing to be in this study and signing this form, you are giving us your permission where needed to use and share your health information as described in this form.	HIP-(2) HIP-(6) HIP-(8) Pt2-(1)	This paragraph provides the reason for the use and disclosure (using the phrase "to do this study" to refer to descriptions in other parts of the consent form) and clearly states that the subject is authorizing the study team to use and disclose their PHI by signing the consent form.

Health information that might be used or given out during this research includes:
• Information that is in your hospital or office health records. The records we will use or give out are those related to the aims, conduct, and monitoring of the research study.
• Health information from tests, procedures, visits, interviews, or forms filled out as part of this research study.
• [Note to investigator: Include this closed bullet and all applicable open bullet(s) if the study involves any of the following types of information.] The health information specifically includes:
  • Mental health communications (with a psychiatrist, psychologist, clinical nurse specialist, marriage-, family-, rehabilitation-, or mental-health-counselor, or educational psychologist)
  • Domestic violence counseling
  • Social work communications
  • Rape victim counseling
  • HIV/AIDS information
	CR-(1)
	HIP-(1)
	Pt2-(1)
	Pt2-(2)
		This paragraph provides the description of the information to be used or disclosed. The third bullet is included if certain sensitive types of information are involved, to provide the potential subject with information that might affect their decision about participating in the study. Besides the Part 2 requirements for alcohol or drug use (HHS, 2018a, §2.22), this template includes additional categories of sensitive information for which specific written permission must be obtained to disclose under Massachusetts laws (Commonwealth of Mass., n.d.).

• Sexually transmitted disease information • Communicable disease information • [IMPORTANT NOTE: Specific written consent is required if the study intends to further disclose alcohol or drug use information.] Alcohol or drug use disorder treatment records about: *list of specific data to be used and shared* • Genetic testing		
The reasons that your health information might be used or given out to others are: • To do the research described here. • To make sure we do the research according to certain standards set by ethics, law, and quality groups. • To comply with laws and regulations. This includes safety-related information. As we explained above, we also have to give out any information from you about: *list of information requiring mandatory reporting such as child abuse or neglect; elder abuse; specific reportable diseases; harm to self or others*.	HIP-(4) Pt2-(2) CA-(2)(a)	This paragraph provides more detail about the reasons for the use and disclosure in addition to the introductory paragraph, and repeats the important information about mandatory reporting, if applicable.

The people and groups that may use or give out your health information are: • Researchers involved in this research study from Boston Medical Center, Boston University, and/or other organizations. • Other people within Boston Medical Center and Boston University who may need to access your health information to do their jobs such as for treatment, research administration, payment, billing, or health care operations • People or groups that the researchers use to help conduct the study or to provide oversight for the study • The Institutional Review Board that oversees the research and other people or groups that are part of the Human Research Protection Program that oversees the research • Research monitors, reviewers, or accreditation agencies and other people or groups that oversee research information and the safety of the study • The sponsor(s) of the research study, listed on the first page, and people or groups they hire to help them do the research	HIP-(2) HIP-(3) Pt2-(2) CA-(2)(a)	This paragraph identifies the class of persons to whom PHI may be disclosed, and again mentions mandatory reporting, if applicable. The statement in the second bullet about using the information for treatment, billing, or operations is not required because such use is allowed under HIPAA without consent or authorization. The statement is included here for consistency with the reference to placing the research information in the medical record in the Confidentiality section to meet the requirement under the Cures Act for obtaining consent for the use or disclosure of research information for treatment of the individual. Any of the last four bullets may be omitted by the investigator if not relevant to the particular study.

• Public health and safety authorities who receive our reports about: *list information such as child abuse or neglect; elder abuse; specific reportable diseases; harm to self or others* • [Note to investigator: Include if applicable; otherwise delete bullet:] A list of other group(s) that will have access to the subject's health information		
We ask anyone who gets your health information from us to protect the privacy of your information. However, we cannot control how they may use or share your health information. We cannot promise that they will keep it completely private.	HIP-(9) CA-(4)	This paragraph complies with the HIPAA requirement HIP-(9) to communicate that PHI may not be covered by HIPAA after being disclosed, but also indicates that the recipients will be asked to protect the information, as is also described in the fourth paragraph of the Confidentiality section.
The time period for using or giving out your health information: • Because research is an ongoing process, we cannot give you an exact date when we will either destroy or stop using or sharing your health information	HIP-(5)	This paragraph takes advantage of the ability to have an indefinite expiration date for authorizations for research.

Your privacy rights are: • You have the right not to sign this form that allows us to use and give out your health information for research. If you do not sign this form, you cannot be in the research. This is because we need to use the health information to do the research. Your decision not to sign the form will not affect any treatment, health care, enrollment in health plans, or eligibility for benefits. • You have the right to withdraw your permission to use or share your health information in this research study. If you want to withdraw your permission, you must write a letter to the Principal Investigator at the address listed on the first page of this form. If you withdraw your permission, you will not be able to take back information that has already been used or shared with others. This includes information used or shared to do the research study or to be sure the research is safe and of high quality. If you withdraw your permission, you cannot continue to be in the study.	HIP-(7) HIP-(8)	This paragraph implements HIPAA requirements HIP-(7) (the right to revoke the authorization in writing) and HIP-(8) (the consequences of not providing authorization), as well as providing information about the individual's ability to see information from their medical records, after the study is over (to preserve blinding). The introductory wording connects signing the consent form to providing authorization.

• When the study has been completed for everyone, you have the right to request access to the health information that we used or shared to make your treatment or payment decisions. If you ask for research information that is not in your medical record, we might not give it to you, but we will explain why not. You may use the contact information on the first page of this form to find out how to get your health information. You may also contact the HIPAA Privacy Officer at Boston Medical Center at: DG-privacyofficer@bmc.org or at Boston University at HIPAA@BU.EDU.		

Table 5. Consent Form Template Signature Section

Paragraph	Requirements	Comments
By signing this consent form, you are indicating that: • you have read this form (or it has been read to you) • your questions have been answered to your satisfaction • you voluntarily agree to participate in this research study • you permit the use and release of information that may identify you as described, including your health information	HIP-(6) CA-(2)(c)	The last bullet in this paragraph again makes explicit that the subject or legally authorized representative is consenting to/authorizing certain disclosures of their research information. This bullet appears even on consent forms that do not include a HIPAA authorization or have a Certificate of Confidentiality, because it is appropriate to reinforce that participating in the study involves gathering and using personal information.

Discussion

This process of producing the template was considered complete when the IRB Executive Board approved the template. The input of the community member was particularly valuable in assessing the understandability of the language. The other Executive Board members, including highly experienced Chairs and the IRB Director, agreed that the template was in compliance with applicable requirements for describing privacy and confidentiality in consent forms, and that the integrated discussion was an improvement over the previous template's approach of having a separate section for each requirement.

Four issues were particularly challenging to address, three because of tension between the requirements, and the fourth because of the unfamiliar concept of Certificates of Confidentiality.

The first issue was the requirement under the Common Rule for a statement about future uses of deidentified data (HHS, 2018b, §46.116[b][9][i]) versus the Cures Act's very expansive definition of what makes data identifiable (Cures Act, 2016; Wolf & Beskow, 2018). The final template addressed this issue by the following language in the Confidentiality section: "We will share research data where we have removed anything that we think would show your identity. There still may be a small chance that someone could figure out that the information is about you." The first sentence contains the required Common Rule statement, and the second sentence has the effect of obtaining consent for sharing information that could be considered identifiable under the Cures Act.

The second issue was that the subject's consent for research information to be shared for medical treatment is required under the Cures Act but not under HIPAA. The final template addressed the requirement for consent by placing the following language in the Confidentiality section for studies with a Certificate of Confidentiality: "We will record information from this study in your medical record, such as information related to your medical care." In the HIPAA section, although authorization/consent is not required to use or disclose information for treatment, to maintain consistency with the Confidentiality section, the final template included the following bullet in the list of people who may use or disclose PHI: "Other people within Boston Medical Center and Boston University who may need to access your health information to do their jobs such as for treatment, research administration, payment, billing, or health care operations."

The third issue was the requirement under HIPAA to state that HIPAA protections do not necessarily apply after information has been disclosed (HHS, 2000b, §164.508[c][2][iii]) versus the Cures Act requirement that the Certificate of Confidentiality protections apply to all copies of the research data disclosed for research purposes (but not for medical treatment; HHS, 1944, §241[d][1][F]). The protections for information that has been shared for research purposes were addressed by the following statement in the Confidentiality section in the final template (for all studies, whether or not they have a Certificate of Confidentiality): "If you agree to be in the study and sign this form, we will share information and biological samples that may show your identity with the following groups of people: ...People who will get information and biological samples from us: name(s) and affiliation(s). These people are expected to protect your information and biological samples in the same way we protect it." The non-protected status of information

disclosed for treatment purposes was addressed by the following statement in the Confidentiality section (for studies with Certificates of Confidentiality): "You should know that once information has been put into your medical records, it is not covered by the CoC. However, information in your medical records is protected in other ways." The requirement to state that HIPAA may not apply when information is disclosed from the Covered Entity was addressed by the following statement in the HIPAA section: "We ask anyone who gets your health information from us to protect the privacy of your information. However, we cannot control how they may use or share your health information. We cannot promise that they will keep it completely private." This statement in the HIPAA section brings forward the concept from the Confidentiality section that the recipients of the research data are expected to protect the data, before adding the caveat that confidentiality is not guaranteed.

The fourth issue was describing the protections afforded by a Certificate of Confidentiality in a way that avoided conveying the idea that a subpoena of research records was likely. In our and other's experiences (Wolf & Beskow, 2018; Check, Wolf, Dame, & Beskow, 2014), potential subjects can be confused about why their research information might be incriminating enough to be subpoenaed when discussing a consent form that contains the standard NIH Certificate of Confidentiality consent language (NIH, 2017c). If the study does not collect data that a subject would consider sensitive, and has a Certificate of Confidentiality only because it is funded by NIH, as in the example discussed in this paper, the final template states: "All studies funded by the National Institutes of Health that involve identifiable information or biological samples are covered by a CoC. ... Even if someone tries to get your information or biological samples in connection with a legal proceeding, we cannot give it to them." In order to minimize the discussion of legal proceedings, the exception that subjects can give permission for release in legal proceedings is not called out explicitly, but is conveyed by two other statements: "The CoC does not prevent you from sharing your own research information," and "If you agree to be in the study and sign this form, we will share information and biological samples that may show your identity with the following groups of people: ... Any people who you give us separate permission to share your information." One helpful change in the Cures Act (2016) is that we no longer have to consider mandatory reporting under state laws as "voluntary," because "required by law" state reporting is an exclusion from the disclosure prohibitions of a Certificate of Confidentiality (Wolf & Beskow, 2018; HHS, 1944, §241[d][1][C][i]). In our experience, describing mandatory reporting as "voluntary" was confusing to our investigators, many of who are mandatory reporters under various state abuse and disease reporting laws (Commonwealth of Mass., n.d.).

Due to the inconsistent requirements and complex concepts required to be conveyed, writing these sections of the consent form in simple language was also challenging. The attempt to reduce the reading level of the template, a well-known concern for confidentiality language (Wolf, Dame, & Beskow, 2018; Check, 2014), was only partially successful: the paragraphs ranged from the 8th to the 10th grade Flesch-Kincaid reading level, compared to the 19th grade reading level of the suggested language on the NIH Certificate of Confidentiality website (Wolf & Beskow, 2018). In addition, some redundancy remained, especially in statements about who will see identifiable information and the exceptions to confidentiality if research information will be subject to mandatory reporting requirements.

Conclusions

Although we could have been compliant with the various requirements by simply adding the Certificate of Confidentiality language as another section of our consent form templates, we set a goal of providing an understandable discussion of the privacy and confidentiality provisions to our research subjects, which still met all regulatory requirements for a valid consent and authorization. We did not have the resources to undertake a study to assess research subjects' understanding of confidentiality protections after consent processes using this and other language. However, the individuals involved in the development and review of the language had extensive experience in human subjects protection, and the final approval was from the IRB Executive Board that included a community member.

Our process and the resulting language (available on our website: http://www.bumc.bu.edu/irb/inspir-ii/irb-templates/) is only one way to integrate the varying requirements, and other solutions are certainly possible. We hope that this example may encourage other IRBs to explore the possibility of improving the understandability of the privacy and consent sections of consent forms.

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Utilization of a Paired Comparison Analysis Framework to Inform Decision-Making and the Prioritization of Projects and Initiatives in a Highly Matrixed Clinical Research Program

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Abstract: *Project prioritization is often an arduous task for any organization. This is particularly evident in large, complex organizations with matrixed management structures, such as the VA Cooperative Studies Program (CSP). CSP is responsible for the planning and conduct of large multicenter clinical trials and epidemiological studies in the Department of Veterans Affairs (VA). CSP Health System Specialists (HSSs) have the primary responsibilities of facilitating alignment and coordination of program-level activities, and leading projects and initiatives to meet the goals of this clinical research program. There is an abundance of literature on Paired Comparison (PC) analyses to inform decision-making, but there is limited publicly available information on its use in clinical research administration settings. The purpose of this project was to determine the effectiveness of a PC analyses framework to inform decision-making in the context of the prioritization of projects assigned to or initiated by the CSP HSS group. Participants were nine HSSs that represented 9 of the 11 VA CSP Centers: 1 Clinical Research Pharmacy Coordinating Center (CRPCC), 3 Epidemiology*

Coordinating (EC) Centers, and 5 Clinical Trial (CC) Coordinating Centers. The CSP Program Manager also participated in this effort. Members were instructed by the HSS facilitator to complete two different versions of the PC worksheet in order to gain experience with using the PC method and to become familiar with its prioritization properties. The template for the PC worksheets was downloaded from www.mindtools.com. Participants were instructed to compare and rank predetermined values during the Values Paired Comparison exercise and projects of interest during the project Paired Comparison exercise. The Values PC exercise resulted in a clear ranking of the group's shared values, with "Safety" rising to the top. The subsequent results of the Project PC exercise, when stratified across the "EC HSSs" and "CC HSSs", showed that EC HSSs placed a higher value on projects that provided training for their role, while the CC HSSs placed higher value on projects that attempted to address program-level issues. When all participant scorings were tabulated together, three projects aimed at addressing program-level issues clearly rose to the forefront. This effort successfully utilized the PC analysis framework to prioritize a list of HSS projects. Using this framework allowed participants to prioritize a list of HSS projects. The framework also enabled the HSS group to identify shared values and to use them to assess the urgency and feasibility of group-assigned projects prior to investing time, effort, and funding in them. Lastly, this framework informed the need for further clarification and evaluation of identified projects as critical steps in project prioritization. There are numerous challenges to effectively performing decision-making in the context of prioritizing organizational projects, particularly in clinical research administration where shifting priorities are a constant. Therefore, the strategies outlined here may be beneficial and transferable to other clinical research administration settings, and beyond.

Keywords: *Strategy, Decision-Making, Clinical Research Administration, VA, CSP*

Abbreviations

CSP	*Cooperative Studies Program*
ORD	*Office of Research and Development*
VA	*Department of Veterans Affairs*
VAMCs	*VA Medical Centers*
HSS	*CSP Health Systems Specialist*
PC	*Paired Comparison*
CRPCC	*Clinical Research Pharmacy Coordinating Center*
CC	*Clinical Trial Coordinating Center*
EC	*Epidemiology Coordinating Center*
SMART	*Site Monitoring, Auditing and Resource Team*

Background

Decision-making and prioritization of projects and initiatives prove to be arduous tasks for any organization. In part, this is due to the need to simultaneously determine and evaluate the potential consequences and downstream effects of those choices during decision-making and prioritization efforts (Saaty, 2008; Simon, 1979). This observation is particularly salient in large, complex organizations with matrix management structures (Davis & Lawrence, 1978). The area of research administration is not immune to these challenges and in actuality, is notably impacted by them due to the nature of the field with regards to frequently changing priorities, matrixed management structures, and limited research funding opportunities (Thom et al., 2014). Clinical research administrators often must make decisions and prioritize projects under the aforementioned conditions and may be better prepared to do so by using a methodology that is structured, categorized, and inclusive of multiple stakeholder perspectives as these criteria have been demonstrated as critical components for decision-making in the context of the prioritization of initiatives (Carnero & Gomez, 2016; Mitton & Patten, 2004; Tromp & Baltussen, 2012). These factors are paramount to increasing the likelihood of an initiative's completion and/or sustainability, and the overall operational efficiency of an organization. There is an abundance of literature on paired comparison analyses to inform decision-making but there is a limited amount of publicly available information on its use in research administration settings (Bradley & Terry, 1952; Ock, Yi, Ahn, & Jo, 2016; Torrens & Smith, 2013; Lorio, Martinson, & Ferrara, 2016).

The Department of Veterans Affairs (VA) is the United States' largest integrated healthcare system and provides comprehensive care to more than 8.9 million Veterans each year (2017). The Cooperative Studies Program (CSP), a division of the Department of Veterans Affairs (VA) Office of Research and Development (ORD), was established as a clinical research infrastructure to provide coordination and enable cooperation on multi-site clinical trials and epidemiological studies that fall within the purview of VA (2018a). The first VA Cooperative Study was conducted in 1946 to evaluate the efficacy of various drugs, including the antibiotic streptomycin, in the treatment of tuberculosis for 10,000 Veterans with this condition; the results of this study revolutionized the treatment of tuberculosis and led to the development of an innovative method for testing the effectiveness of new drugs (2018b). Currently, the program consists of eleven coordinating centers that facilitate the execution of clinical trials and epidemiological studies through the provision of project management, statistical, drug and device management, and regulatory and compliance support, with each center having a primary focus on either clinical trials or epidemiological studies (VA Office of Research & Development, 2013). CSP also houses a pharmacogenomics laboratory that was created to support ongoing and future pharmacogenomics studies and clinical trials within the program, as well as a consortium of VA medical centers (VAMCs) that have teams (nodes) in place dedicated to enhancing the overall performance, compliance, and management of CSP multi-site research (VA, 2018c; Condon et al., 2017; Johnson et al., 2018). CSP Health Systems Specialists (HSSs) have the primary responsibilities of facilitating the alignment and coordination of activities across the program, leading initiatives to meet program goals, and communicating the larger CSP vision and direction to colleagues across the program. This position also makes recommendations on

resource allocation and project identification and prioritization to leadership at both the CSP national program level and the Center level. Therefore, an organized, methodological approach to decision-making, prioritization of initiatives, and resource allocation is vital to those individuals serving in the HSS role, as well as to research administrators in other settings.

The purpose of this project was to determine the feasibility of utilizing a paired comparison analyses framework to inform decision-making in the context of prioritizing projects and initiatives assigned to or initiated by the CSP HSS group. The findings may inform individuals or groups in research administration and leadership roles seeking to develop, select, and prioritize projects within their organizations.

Methods

Participants

The participants in this study were nine HSSs that each represented one of the eleven VA CSP Coordinating Centers (three Epidemiology Coordinating Centers (ECs), five Clinical Trial Coordinating Centers (CCs), and one Clinical Research Pharmacy Coordinating Center (CRPCC)), as well as the CSP Program Manager. There were two ECs that did not have representation on the HSS group and subsequently, did not participate or have direct input during this exercise. The individual administering this study was the HSS facilitator and their primary role was to coordinate exercises whose objectives were to strengthen leadership and administrative skills among the participants.

Prioritization Tool

The primary instrument used in this initiative was the Paired Comparison (PC) Worksheet (2018d). This worksheet was selected to be used as a tool during the creation of a shared framework for comparing values and projects among the participants in order to translate prioritization and critical thinking behavior to daily work life. There are six steps associated with successful use of the PC worksheet and these were all followed during this process. Step one indicates populating the worksheet with all options targeted for comparison. After all options have been identified, step two specifies listing the options in the cells vertically and horizontally across the gridded worksheet so that there are two of each option. The structure of the worksheet is comprised such that any areas where an option would be compared with itself or with another option more than once is negated, therefore, each option is compared with all other options only once. Step three details comparing the rows against the columns and assigning the option that is of higher priority and importance to the blank cell. Steps four and five entail scoring and totaling the score for each option. The options were scored as "0 = no more important", "1 = slightly more important", "2 = moderately more important", and "3 = significantly more important" in relevance to the other options. Once the options were tallied and scored, a clear ranking was derived. Step six allows time in the process for any adjustments to be made that the participant or facilitator deems necessary.

Prioritization Process

Prioritization of Values. The participants in this exercise came from diverse backgrounds with regards to their expertise and roles at the VA CSP Coordinating Centers. Considering this diversity, the HSS facilitator developed a list of values based on the HSS group's role in the organization so that all projects could be evaluated in the context of a specified values framework. This approach also enabled the participants to become comfortable and familiar with the PC worksheet. The values chosen by the HSS facilitator included the factors that HSSs were most commonly faced with when evaluating the feasibility of executing a project. These factors are commonly associated with decision-making in research administration and leadership roles outside of the VA CSP setting, and include Risk, Feasibility, Cost/Time, among others (Deeming et al., 2018; Baskerville, 1991; Layard & Glaister, 1994; Morgan, Hejdenberg, Hinrichs-Krapels, & Armstrong, 2018; Kuruvilla, Mays, Pleasant, & Walt, 2006; Henderson, 2001). These factors were then populated into the rows and columns of an abbreviated version of the Paired Comparison worksheet in Table 1. This worksheet was then sent to the participants by email and they were instructed to compare the values against each other and to return the document to the facilitator. Completion of the values comparison resulted in a defined ranking of the most important value for each participant. After receipt of the completed worksheets, the facilitator tabulated the results and communicated them to the group during their next scheduled conference call. The results were discussed and the group agreed that the rating of the values was accurate. The members were then advised that they would be receiving a follow-up prioritization worksheet containing a list of HSS projects.

Table 1. Values Paired Comparison Worksheet.

Option	A. Impact	B. Effort	C. Risk	D. Feasibility	E. Cost/Time
A. Impact					
B. Effort					
C. Risk *(Of doing it or not doing it)*					
D. Feasibility *(Can we? Should we? Will we?)*					
E. Cost/Time					

Prioritization of Projects. The facilitator populated the same PC worksheet template (Table 2) with projects that were listed as standing items on the HSS monthly call agenda. Projects were also selected based on feedback from individual HSS group members, suggestions by other groups or individuals from across the program, or communications from CSP leadership to the HSS group regarding program-level challenges that were of enough importance to request that they be addressed. The projects that were selected for the PC work were relatable to all participants so that meaningful selection could occur for each participant. The list of projects that were populated in the rows and columns of the PC worksheet included Document Review & Mapping, Improve Smart Communication, Document Writing Process, Facilitator Guidelines, Training Plan,

Improve Internal Review (IR) Process, Determine Virtual Meetings, and CSP Publications. The document was then distributed to the participants by email and the participants were then instructed to follow the same methodology as previously executed. The PC worksheet was then used to compare all projects in the list against each other. Participants determined which projects were of higher priority and importance as compared to other projects, all while keeping the shared values and results from the previous exercise in mind and as a reference. The results were presented to the participants during a subsequently scheduled conference call and the ranking that was tabulated by the HSS facilitator was discussed.

Table 2. Projects Paired Comparison Worksheet.

Option	A Document Review & Mapping	B Improve SMART Comm.	C Document Writing Process	D Facilitator Guidelines	E Training Plan	F Improve IR Process	G Determine Virtual Meetings	H CSP Publications
A Document Review & Mapping								
B Imp. SMART Comm.								
C Document Writing Process								
D Facilitator Guidelines								
E Training Plan								
F Improve IR Process								

Prioritization of Projects Based on Values. During the conference call that followed the Prioritization of Projects PC exercise, one group member provided feedback that indicated the PC worksheet was not sufficiently weighted to account for the differences between projects, based on values. This individual hypothesized that some values may or may not account for the differences seen in the rankings of projects between HSS individuals. Based on that feedback, the HSS facilitator created a grid similar to the PC worksheet template and it was used to compare the values against the top five projects using a Likert scale (Table 3). The values and projects were aligned across the rows and columns to simulate an experience comparable to the prioritization exercises that were completed with the first two PC worksheets. This grid was distributed to the group members by email and the directions remained the same for comparing and ranking the values and projects as before. Once responses were received, weighted results were tabulated by

the HSS facilitator and communicated on the next scheduled conference call.

Table 3. Values versus Projects.

	FACTORS					
HSS PROJECTS	**RISK = 5 (factor weight)** The risk to the program is high if this project is not completed. 1 = Strongly Disagree 5 = Strongly Agree	**FEASIBILITY = 4** With our current resources and influence we are likely to complete this project. 1 = Strongly Disagree 5 = Strongly Agree	**IMPACT = 3** If we completed this project, it would have a positive impact on the Program. 1=Strongly Disagree 5 = Strongly Agree	**COST/TIME = 2** The cost in time and money to complete this project is low. 1 = Strongly Disagree 5 = Strongly Agree	**EFFORT = 1** The project can be completed in less than 3 months. 1 = Strongly Disagree 5 = Strongly Agree	**Total** Multiply the **Factor Weight** by your **Likert scale rating.** Enter subtotals in each box. Add Subtotals across to achieve Total for each row.
1. Determine Meetings to Hold Virtually	1 2 3 4 5 Subtotal: [=Factor*rating]	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	Total:
2. Improve Smart Communication	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	
3. Document Review & Mapping	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	
4. Document Writing Process	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	
5. Improve IR Process	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	

Results

Figure 1 shows the ranking of values from the first Values Paired Comparison exercise the HSS group was instructed to participate in. These values are ranked from most important (1) to least important (5), based on a scale from 1-5. The most important value chosen by the group during this exercise was "Risk", while the least important value was identified as "Effort".

Values Comparison	Rank
Risk	1
Feasibility	2
Impact	3
Cost/Time	4
Effort	5

Figure 1. Values Ranking Among all HSSs.

The results from the second exercise, the Project Paired Comparison worksheet, are displayed in Figure 2. These results show the complete ranking of the projects across all nine of the HSSs and the CSP program manager. The Document Writing process was originally considered by the group to be a high priority project, but once the PC framework was applied, the results showed that it had fallen in importance to the fourth spot. Once these results were stratified across the two types of HSS employees, "EC HSSs" and "CC HSSs", results showed that the EC HSSs placed higher value on the project "Training Plan," which would provide additional training for their role, i.e., the HSS training plan. Additionally, the CC HSSs placed higher value on projects aimed at addressing issues that impacted the entire program, such as "Improving SMART Communication" and "Determine Meetings to Hold Virtually". When all participant scorings were tabulated together, three projects aimed at addressing program-level issues clearly rose to the forefront.

Option	Total	Rank
C Document Writing Process	46	1
G Determine Meetings to Hold Virtually	44	2
B Improve SMART Communication	44	3
A Document Review & Mapping	42	4
F Improve IR Process	37	5
H CSP Publications	16	6
D Facilitator Guidelines	9	7
E HSS Training Plan	6	8

Figure 2. Project Ranking Among all HSSs.

The results from the last group exercise, ranking of projects by values, is shown in Figure 3. The projects aimed at addressing program-level issues rose to the top, with the highest-ranking project being "Determine Meetings to Hold Virtually". This project had previously been given high-priority by VA leadership due to the significant costs (flights, lodging, per diem, etc.) of having large, in-person meetings. Additionally, the projects "Improve SMART Communication" and "Document Review and Mapping" were among the top three weighted results, which were two of the projects that would impact the entire program. The "Document Writing Process" fell in rank to the fourth spot. There was a 90% response rate for the distributed worksheets used by the facilitator for scoring during this program.

Weighted Comparison	Rank
Determine Meetings to Hold Virtually	1
Improve Smart Communication	2
Document Review & Mapping	3
Document Writing Process	4
Improve IR Process	5

Figure 3. Weighted Ranking of Projects by Values Among all HSSs.

Discussion

Decision-making and prioritization of projects and initiatives are often challenging and complex responsibilities for organizations to undertake (Salihu, Salinas-Miranda, Paothong, Wang, & King, 2015; Simons, Benders, Bergs, Marneffe, & Vandijck, 2016). Strategies and tools that provide a structured framework for accomplishing these tasks can be beneficial in mitigating the burden and risks associated with these efforts. The collaborative nature of research is increasing in the form of research networks and other partnerships; therefore, research administrators will benefit from identifying and developing processes for group decision-making and other

aspects of collaboration that warrant structured approaches for the prioritization of tasks (Adams, 2012; Bozeman, Gaughan, Youtie, Slade, & Rimes, 2016; Fagan et al., 2018). Even in the context of established research administration leadership and management teams, decision-making, the prioritization of projects, and resource allocation prove to be challenging tasks due to diminishing funding and rising expectations (National Science Board [NSB], 2012). This initiative demonstrates that the utilization of a paired comparison analyses framework to inform decision-making as it relates to the selection and prioritization of projects was effective in a highly matrixed clinical research program. Therefore, the use of this tool may be beneficial to other research administrators that are faced with similar challenges as they work to manage the execution of research studies and initiatives at their respective institutions. The use of this framework was also effective in prompting discussion that clarified ambiguity related to ill-defined project definitions and scope.

There are several publications that report the use of a paired comparison analyses framework to improve the selection and prioritization process of projects and initiatives in healthcare, business, and other settings (Canero & Gomez, 2016; Mennecke, Townsend, Hayes, & Lonergan, 2007; Ock et al., 2016; R. Subramoniam, Huisingh, Chinnam, & S. Subramoniam, 2013), but there is a limited amount of publicly available information on the use of the tool in a clinical research administration setting. We are therefore unable to compare the results of this project with previous initiatives but can address some common themes that occurred over the course of our work.

The use of this framework confirmed the need for more clarity around projects that the HSS group included as a part of this effort. It is critical that clear, specific project parameters such as the problem statement, scope, and timeline are established prior to beginning work on any project in order to increase the efficiency of its execution, as well as to eliminate ambiguity related to its desired outcome. For example, there was considerable ambiguity within the group surrounding the third ranked project, "Improve SMART Communication". This project was initially suggested to the HSS group by others in CSP as being one that would be beneficial to the program to undertake. Within the HSS group alone, there were several interpretations of what the intended goals of this project were, including improving communication between research study sites and the CSP Site Monitoring, Auditing and Resource Team (SMART) group, as well as improving communication between Coordinating Centers and the CSP SMART group (2018e). Naturally, the differences in interpretation of the project goals led to confusion around what the project execution plan should entail. Utilizing the paired comparison framework necessitated that the HSS group reach back out to those in the program that requested the project for additional details on the problem that it was intended to solve and other specifics related to it. Research administrators are often faced with competing requests from multiple parties for resources, e.g. study sponsors, study sites, internal study teams, etc., for decision-making with regard to taking on projects, and for their expertise on how to manage projects (Sajdyk et al., 2015; Glasgow et al., 2014). This example demonstrates the tool's usefulness in eliciting clarity and specificity of project parameters during the prioritization process for projects that are requested by either a group or individuals for another group to take action on.

It was also of interest to observe that when the results were stratified across the two types of HSS employees, "EC HSSs" and "CC HSSs", they showed that the EC HSSs placed higher

value on the project "Training Plan," which would provide training for their role, i.e., the HSS position training plan. Although there are many similarities between the ECs and CCs in terms of considerations that are involved with executing research studies in their respective settings, there are also numerous differences between them due to the nuances that exist with conducting epidemiologic, observational studies, as opposed to randomized clinical trials. The CSP HSS group started with representation solely from the CCs and the EC HSS members have only been a part of the HSS group for a couple of years to date. Due to that sequence of events and the origin of the group's roster, it is possible that EC HSS members desired additional training on the responsibilities of the HSS role and what it entailed given that the they had not functioned in the position previously. The addition of EC representation to the HSS group has been beneficial to the larger program because it provided another venue for input from the ECs in project decision-making and prioritization efforts for program-level initiatives that, prior to them joining the group, may not have been considered. This finding also had great significance because it highlighted a perceived need for supplementary training from members of the HSS group, which from an administrative perspective, is a critical area to be addressed. Competency-based training and professional development is vital to the success of the clinical research enterprise (Behar-Horenstein et al., 2017; Arango et al., 2016) and research administrators are often involved with staff development and must organize and coordinate various trainings for the staff that they oversee and/or work with. Utilization of the paired comparison analysis framework demonstrated that there was an additional benefit to its use, in the form of establishing that there was a desire for additional training from our personnel. Furthermore, the most important aspect of any organization is its staff, and administrators have an obligation to invest in staff development and provide adequate training to their personnel to increase the likelihood of their success and value to the institution (Sung & Choi, 2014; Gesme, Towle, & Wiseman, 2010; Elnaga & Imran, 2013).

Lastly, our use of the paired comparison analysis framework was an effective approach for acquiring the views and perspectives of a collective of research administrators in order to inform prioritization and project selection within a clinical research program. The expertise of the CSP HSS group spans across many disciplines including project management, compliance, quality management, law, and administration. Therefore, in the absence of using a structured, methodological process for prioritizing and making decisions on the projects that were assigned to or initiated by the group, the likelihood that decisions might have been made that favored a particular discipline might have been higher. CSP Health Systems Specialists (HSSs) have the primary responsibilities of facilitating alignment and coordination of activities across the program, leading initiatives to meet program goals, and communicating the larger CSP vision and direction to others across the program. Therefore, it is paramount that any decisions that the group makes concerning projects or initiatives are formed through "systems thinking" (Adam & de Savigny, 2012; Leischow et al., 2008) and have the potential to have the highest positive impact and greatest benefit to the entire program. The management of research activities, particularly those involving human subjects, is complex and inclusive of a variety of responsibilities including ensuring compliance with research regulations and policies, managing the diversification of funding portfolios, and facilitating collaboration amongst researchers (Bian et al., 2014; Falk-Krzesinski & Tobin, 2015; Zikos, Diomidous, & Mantas, 2012). This framework facilitates broad, high-level thinking by

incorporating a variety of perspectives into decision-making and prioritization efforts and would likely be useful to research administrators in any setting.

There are several limitations of our work that may present challenges to its implementation in other settings. The first was that it was difficult to identify the individuals and/or groups who originally suggested the projects to the HSS group. This situation made it difficult to determine what the true intent of the requested projects were in terms of what they were intended to achieve. Ideally, an organization's process for evaluating and prioritizing projects and initiatives should include "the voice of the customer" (Boll, Rubin, Heye & Pierce, 2017; Nazi, Turvey, Klein, & Hogan, 2018; Valdez et al., 2018). Another limitation was that this process did not involve all relevant stakeholders across CSP. For this effort, there was representation from nine of the eleven VA CSP Coordinating Centers; two Epidemiology Coordinating Centers (ECs) were not a part of the process. The PC framework may have yielded different results had those two centers participated. Furthermore, there are several functional subdomains in the program with distinct subject matter expertise (e.g. project management, biostatistics, finance, etc.) who were not included in this process. Although the CSP HSSs work closely with these groups in varying capacities, the subdomains did not have direct participation in this effort. Had they participated in the exercises directly, results may have differed. There are potential options that the HSS group could undertake to address the lack of full CSP representation in this process. The first would involve the HSS group working with the leadership teams at the two ECs that do not currently have representation on the HSS group to identify two individuals (one from each EC) to serve as HSSs. Since the HSS position is a funded position, there would also need to be support from CSP leadership to provide funding to those two ECs for them to be able to hire and fill those positions. Secondly, the HSS group could invite subject matter experts from the relevant CSP subdomains to participate in the decision-making and prioritization process for projects when appropriate. For example, if the HSS group is tasked with making decisions related to projects that involve finance, project management, and compliance, then additional representation from the relevant CSP subdomains could be requested for their participation in the prioritization process. The sheer size of the CSP (500+ employees) makes having the direct involvement of every CSP employee in this process impractical, but having additional representation from groups or individuals that would be directly impacted by the outcome of any decision made related to a particular project or initiative would improve the overall process. Another potential limitation of our work is related to the setting in which it was conducted and its possible impact on the results of this approach in this setting and others. This initiative was conducted in a clinical research program within a large, integrated healthcare system that is managed by the United States federal government. Therefore, the contributors in this exercise were not impacted by the influence of financial considerations in their decision-making efforts. In other settings, such as business or for-profit healthcare systems, the results of this framework may have been different due to the potential impact of profit and/or revenue on the participants during this activity.

Considering these limitations, our project demonstrated several notable strengths. This activity was novel in that there is a limited amount of publicly available information on the utilization of the paired comparison analyses framework in clinical research administration settings, as determined through a review of publicly available literature. Prior applications of this methodology have been

employed extensively in business and healthcare environments, but not in this specific type of setting. Another strength of this project is that it facilitated the collection of input directly from representatives of the majority of our program's Coordinating Centers. This cross-representation may have increased the likelihood of sustainability for the selected projects. Lastly, the diversity of perspectives and experience of the HSS group was an asset during the exercise and resulting discussions, as well as during additional assessments of the projects. The expertise of the group spans across several disciplines including project management, compliance, quality management, law, and administration. The variety of backgrounds in the group undoubtedly strengthened the paired comparison activity by increasing the breadth of perspectives that contributed to the exercise, and subsequently allowed for decision-making and prioritization that was inclusive of multiple viewpoints.

In summary, utilization of the paired comparison analysis framework was an effective strategy to inform decision-making for the selection, evaluation, and prioritization of projects and initiatives in a highly matrixed clinical research program. Additional work is needed to determine the effectiveness of this strategy in other research organizations, both within and external to the VA. Future work in this area should also involve a more extensive evaluation of the projects that are selected and prioritized when utilizing this framework, in terms of their sustainability and achievement of desired outcomes. The field of research administration is complex and demanding in nature, therefore, any potential tools and approaches that can be utilized to simplify and alleviate its associated challenges would likely prove to be valuable to individuals in these positions.

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AB20 and the California Model Agreement: Insights from Implementation and Streamlining of State Contracting with Academic Institutions

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Abstract: *Prior to the passing of California Assembly Bill 20 (AB20) and the implementation of the California Model Agreement (CMA) in 2015, the proposal and award process for the California public university systems and the state of California was slow-moving, administratively burdensome, and inconsistent in contracting for research, training, and public services. The CMA was developed as a streamlined and collaborative vehicle for the state to conduct business with the University of California (UC) and the California State University (CSU) systems. The CMA has passed its three-year anniversary and has, in general, been effective in both standardizing proposal applications and submissions and in reducing the time and effort required to secure agreement. This study uses a mixed methods research approach using survey and interview instruments to: 1) determine the effectiveness of the current state contracting process in California; 2) identify successes and challenges of implementing this campus-wide pre- and post-award Sponsored Projects model; 3) collect suggested improvements to the process; and 4) offer recommendations for further implementing a model agreement proposal and award process.*

Keywords: *Model Agreement; State of California; Assembly Bill 20 (AB20); University of California (UC) System; California State University (CSU) System; Proposal Process; Award Process*

Background

In Fiscal Year 2006–2007, the University of California and the California State University received approximately six billion dollars ($6,000,000,000) from the State General Fund, through more than 2,500 contracts or contract amendments from state agencies and departments. Prior to AB20 implementation, proposal requirements and contractual terms and conditions differed vastly depending on the state agency, university, university system, and/or the research relationships established by the principal investigator and program officer with state officials. The challenges confronting state agencies and university systems arose from inconsistencies in the language for proposal requirements, slow award processing times, and lengthy contract negotiations. Incomplete or ambiguous internal and external communications presented ongoing issues, along with frequency of revisions. University faculty and research administration staff routinely contended with the length of negotiations, with faculty especially hampered by budget inflexibilities. Proposal and award incongruities, missed project deadlines, and the lack of complete information could result in delays in project start times and report schedules and possible cancellation of proposals and projects. Although many of the contracts contained similar provisions, negotiations and drafting of acceptable terms could take from six months to a year. In many cases, the State bore the costs of both sides in contract negotiations.

California Assembly Bill 20 (AB20) and California Education Code 67327 require the California Department of General Services (DGS) to negotiate model contract terms for use by state agencies that fund research, training, or public service projects conducted by campuses of the UC and CSU systems (Assembly Bill No. 20, 2009). On November 2, 2015, the three parties concluded negotiations and signed a Memorandum of Understanding (MOU) to enact collaborative, expedited proposal processes and agreement templates for new awards from State agencies issued after January 1, 2016 (University of California Office of the President [UCOP], 2016a; 2016b).

The California Model Agreement (CMA) includes both pre-award and post-award models, thereby combining the state's proposal and award processes. Submitted proposal documents make up the actual exhibits that are incorporated into the CMA, and the pre-negotiated model agreement provisions comprise the contractual terms and conditions (UTC-518) (University of California, Berkeley, 2017). The parties' intention is to share full transparency regarding requirements and expectations, from proposal submission to award acceptance. In cases in which the UTC-518 terms and conditions are not adequate due to the needs and/or scope of the research, training, or public services, the CMA allows for a flexible approach to the model agreement in the form of an alternative terms and conditions exhibit (Exhibit G) (UCOP, 2016b; UCOP, 2017). Originally, the key stakeholders involved created a not-yet-adopted *State and University Proposal & Administrative Manual* (SUPAM) that provided details on completing each Model Agreement Exhibit during the proposal submission process as well as award and post-award information and procedures (UCOP, 2016a).

The UC and CSU systems are two of the three segments of California higher education, the third being the California Community Colleges. The UC system was established as the focal point for academic and scientific research within the higher education system. In addition to

bachelor's and master's degrees, the UC grants doctorates and professional degrees. The CSU system grants bachelor's and master's degrees that have a practical career orientation and is the largest four-year public university system in the United States (California State University, 2018). Creating the CMA required the collaboration of these two major multi-campus public university systems (10 UC campuses and 23 CSU campuses) and 168 State Agencies (State of California Agencies, 2017) to examine and significantly change their processes, adopt a new proposal and award business model, and translate that model to their staff and faculty. This article explores the university system view of the CMA at two different data points in the post-implementation process by applying two complementary research methodologies.

State Agency and Research Administration Requirements: A Review of the Literature

Although there is a scarcity of research on this topic, the literature suggests that discussions for streamlining state research administration requirements began between 1986 and 1988 with the creation of the Florida Demonstration Project to develop and test new grants management procedures. The founding members included five major federal research and development agencies—the Department of Energy (DOE), National Science Foundation (NSF), National Institutes of Health (NIH), Office of Naval Research (ONR), and Department of Agriculture (USDA)—as well as the Florida State University System, and the University of Miami (Federal Demonstration Project [FDP], 2018). Eventually, the pilot project led to the implementation of the six-phased Federal Demonstration Partnership (FDP) project, a cooperative initiative designed to reduce the administrative burdens associated with research grants and contracts (FDP, 2018). Between 1990 and 1991, Phase II of the FDP's Government-University-Industry Research Roundtable set up the State-Grantee Relations Task Group to prepare its *Survey of State Requirements Applicable to Externally Funded Research Activities* (FDP, 1990), which discussed state administrative requirements applied to university research (FDP, 1991). Gifford and Scanley (1991) explored the results of the survey and recognized that state and university research requirements were plagued by the same problems experienced between federal agencies and academic institutions: most notably, lack of budget and reporting flexibility, restrictive prior approvals requirements, and lack of pre-award costs mechanisms. Based on questionnaire results, the FDP Task Group was able to improve these research administration systems at the federal level. Future pilot demonstrations were considered at the state level to modify state requirements with grantee institutions for research proposal applications, standardizing grant terms and conditions, eliminating burdensome prior approvals, and creating uniform policies for reimbursement of indirect costs. Over 25 years after these FDP State-Grantee Relations Task Group discussions, the passing of California Assembly Bill 20 and implementation of the California Model Agreement have taken the model of streamlining state and university requirements from concept to completion in the state with the world's fifth largest economy (Associated Press, 2018).

Methodology

This study arose out of a December 2, 2016 survey designed and initiated by the University of California Office of the President (UCOP) and California State University Office of the Chancellor to assess the first year of implementation of AB20. Its purpose was to identify nascent issues and challenges of the CMA and to facilitate discussions of its implementation at the first annual meeting of the University of California, California State University (CSU), and the California Department of General Services (UCOP, 2017). The survey instrument was targeted to approximately 85 individuals in the research administration community, including policymakers, directors, officers, and administrators. (The actual number of subjects who received the survey is indeterminate due to the varied group email dissemination process that was employed by the UCOP.) It was distributed to 10 University of California campuses, 23 California State University campuses, the University of California Office of the President, the California State University Office of the Chancellor, and the UC Division of Agriculture and Natural Resources. The survey included 5-point Likert-type scale questions regarding pre-AB20 implementation workshops; a series of agreement provision rankings with a drop-down menu of 22 pre-populated categories (including a separate option to enter "None") that mirrored the 26 Articles of the CMA, along with accompanying fields for qualitative responses; and a series of "Yes" or "No" questions.

The author secured written approval from both the UCOP Research Policy Office and the California State University's Sponsored Programs Office at its Office of the Chancellor to obtain the raw survey data. Prior to data collection and analysis, it was necessary for the author to complete human research training and certification, apply for Exceptional Principal Investigator status through the UC Berkeley Office of the Vice Chancellor for Research, and submit a research protocol to the UC Berkeley Institutional Review Board. Although the UCOP survey had reached a wide audience, it was clear to the author that a second qualitative interview-based cohort would be needed to target specific areas that the initial survey had not covered.

Concurrently, to meet relevant standards and protocols, the author obtained Collaborative Institutional Training Initiative (CITI Program) certification, Principal Investigator status (April 2017), and UC Berkeley IRB approval (CPHS Protocol #2017-05-9926).

For the second cohort of the study, the author conducted 10 in-depth interviews among UC Berkeley staff and faculty. In the participant pool were supervisors, research administrators, and research faculty, including a principal investigator and a project director. Participants were selected based on their day-to-day administrative or technical experience with the AB20 CMA process. Additionally, only participants with prior research experience and a minimum of two years research experience at UC Berkeley were selected. Interviews lasted 20–30 minutes, with 80% of the interviews conducted in person and the remaining interviews by phone. Informed consent was obtained verbally for all participants.

The second cohort's interview data responses were transcribed by the author. Responses were assigned by words or phrases to coding categories, and textual data including ideas, concepts, and themes were coded to fit the categories and frequency of themes within the responses. Responses that did not appear in multiple interviews were noted accordingly, as were themes that were expressed multiple times during interviews.

Limitations

The author was constrained to a small sample size due to 1) the newness of the AB20 initiative and unfamiliarity with the AB20 CMA process by university staff and faculty, and 2) survey participants selected by the UCOP and the CSU Office of the Chancellor prior to the conception of this study. The author's intention was to conduct a pilot study with both the available UC and CSU data and the in-depth interviews conducted at UC Berkeley. A larger sample size with the inclusion of a broader spectrum of state and university key stakeholders is recommended for a follow-up study.

Analytical Strategy: Survey Group

Descriptive statistics were derived from survey data collected by the UCOP. Frequencies and cross tabulations of the data were generated using Stata Version 12 and Microsoft Excel™. Figures and tables were created using Microsoft Excel™.

Results

Of the approximately 85 targeted subjects, 38% (N=33) completed the survey questions; 55% (N= 18) of respondents were from the CSU system and 45% (N= 15) were from the UC system. The UC responders comprised directors, grants and contracts officers, a manager, and a research analyst. The CSU responders comprised directors, grants and contracts officers, a manager, a vice president, and research analysts.

Fifty-two percent of survey responders also participated in an AB20 Implementation Workshop. The workshop was initiated a few months prior to the inauguration of the CMA to inform staff at both the UC and CSU systems of the upcoming changes to the state proposal and award processes, to ease the transition among research administration staff, and to address any early concerns or uncertainties. Among these workshop participants, 47% (N=8) were from the CSU system and 53% (N=9) were from the UC system. The breakdown of participant statistics is presented in Table 1 below.

Table 1. Percentages of Respondents

	Percentage	**N**
Completed Survey (Response Rate)	38%	33
University System		
CSU	55%	18
UC	45%	15
Workshop Participation		
Yes	52%	17
No	45%	16
Occupation		
Directors	52%	17
Officers	30%	10
Analysts	9%	3
Managers	6%	2
Vice President	3%	1

Source: UCOP AB20 Survey

California Model Agreement Provisions

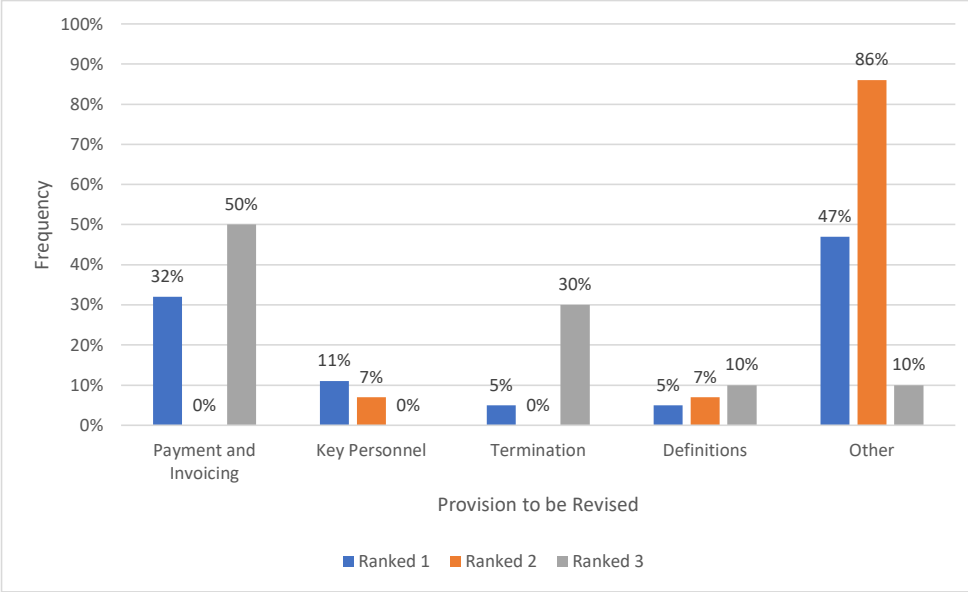
As part of the survey, participants were presented with the 26 provisions of the CMA that potentially posed a significant and/or unintended burden on their university and/or could be easily improved. The provision choices in Table 2 were provided in a drop-down menu with a separate option to enter "None."

Table 2. Top 3 Provisions to be Revised

#	**Clause**
1	Definitions
2	Approval
3	Amendment
4	Liability
5	Conflict of Interest
6	Dispute Resolution
7	Termination
8	Confidential Information
9	Key Personnel
10	Requirements Associated with Funding Sources
11	Sub-awards
12	Budget Contingency Clause
13	Travel
14	Payment & Invoicing
15	Audit
16	Right to Publish
17	Data Rights
18	Copyrights
19	Use of Name and Publicity
20	Access to State Facilities and Computing Systems
21	Notices (and other Standard Provisions 22-26)

Source: UCOP AB20 Survey

Respondents were asked to select the top three provisions that they would like to see revised. Thirty-two percent of the respondents considered Payment & Invoicing as the top provision that needed revising. The predominant provisions considered for revisions (by rankings of 1, 2, or 3) are compared in Figure 1.



Source: UCOP AB20 Survey

Conversely, 42% (N=14) of the respondents reported that they would not change any of the provisions, with 61% (N=9) of the CSU respondents indicating no changes to the CMA provisions were necessary compared to 20% (N=3) of the respondents from the UC system.

Exhibit G: Negotiated Alternate University Terms and Conditions (UTC)

Along with provision revisions, the second focus of the UCOP AB20 CMA survey was to collect data on Exhibit G (Appendix 1). The California Education Code authorizes a flexible or modular alternative for projects in which one or more CMA terms are inappropriate or inadequate for a specific project. These alternative terms and conditions are known as "Exhibit G" under the CMA (UCOP, 2016; UCOP, 2017). Participants were asked which CMA terms and conditions were routinely changed via the Exhibit G vehicle.

Twenty-three percent of responders stated that when receiving an agreement from the State of California with an Exhibit G (Negotiated Alternate UTC Terms), the terms and conditions were most likely to change the CMA terms and conditions significantly. Of those who indicated that changes would result, the most frequently chosen change was Payment & Invoicing (22%). This was followed by Right to Publish, Liability, and Copyrights (at 8% each) (Table 3).

Table 3. Routinely Changed Exhibit G Provisions (Multiple Responses)

Provision	% Responding
Payment & Invoicing	22%
Copyrights	8%
Liability	8%
Right to Publish	8%
Access to State Facilities and Computing Systems	6%
Confidential Information	6%
Data Rights	6%
Requirements Associated with Funding Sources	6%
Sub-awards	6%
Termination	6%
Amendment	3%
Audit	3%
Budget Contingency Clause	3%
Definitions	3%
Key Personnel	3%
Notices	3%
Use of Name and Publicity	3%

Source: UCOP AB20 Survey

Discussion of the Findings: California Model Agreement

The AB20 CMA survey captured the UC and CSU systems' attitudes towards the California Model Agreement nearly one year after implementation. As mandated by the AB20 act, the UC, CSU, and state must meet annually to discuss critical issues regarding the AB20 process and the California Model Agreement Terms and Conditions (UCOP, 2016). The campuses mostly concurred that revisions to the CMA were not a top priority at the 2017 meeting. However, they agreed that Payment & Invoicing terms (a concern of most survey respondents) would be a priority for the next iteration of the Model Agreement.

The majority of negative responses to receiving non-favorable terms and conditions under Exhibit G points to a need to improve or clarify its function within the CMA, and remains a point of contention between the university systems and the state. The UCOP and CSU Office of the Chancellor continue to request input from various constituencies including state agencies and CSU/UC campuses via annual surveys to negotiate and make adjustments to the CMA terms and templates.

Analysis of the Data: Interview Cohort

Descriptive statistics were derived from human subject interview data collected, transcribed, and coded by the Investigator. Frequencies and figures were created using Microsoft Excel™.

Faculty Participants

The three faculty participants included a principal investigator, a project director, and a program director. The average number of years of combined research experience was 14 years between 13 and 15 years of research experience). The average level of AB20 CMA knowledge (based on a scale of 1 to 10) was 6.

Research Administration Participants

The seven research administration interview respondents included three officers, two directors, a team leader, and a supervisor. The average of combined research administration experience was 12 years (between 2 and 27 years of research administration experience). The average level of AB20 CMA knowledge was 7.

Overall Responses

Interview responses pointed to the following Pre-AB20 successes:

1. Strong working relationships built between State and University (43%);
2. Proposal requirement flexibility (depending on which state agency and with which state contact participants were working) (21%);
3. Development of a Model (On-Call) Agreement between a university and a single state agency (Caltrans) (21%) (State of California Agencies, 2017); and
4. Large number of proposals funded (14%).

It should be noted that one respondent stated that there were no pre-AB20 successes (not included in the percentages).

Participants named inconsistent proposal and/or contract terms or requirements among the primary pre-AB20 challenges in their responses. Budget inflexibility, long negotiation and award time, and lack of internal and external communication followed as the top challenges (Figure 2).

Educating the state on how the AB20 CMA process works was the main critical issue in post-AB20 CMA implementation responses as well as both post-AB20 CMA recommendations and post-AB20 CMA improvements responses. Other major critical issues were the lack of a standardized indirect cost rate and, for research administration respondents, the inclusion of Exhibit G allowing for alternate or modular CMA terms. Some respondents also mentioned the need to provide more education on how the AB20 CMA process works within the university setting.

The author found interesting the differences when faculty and research administration members' responses to the interview items were compared. The following section is a detailed comparison

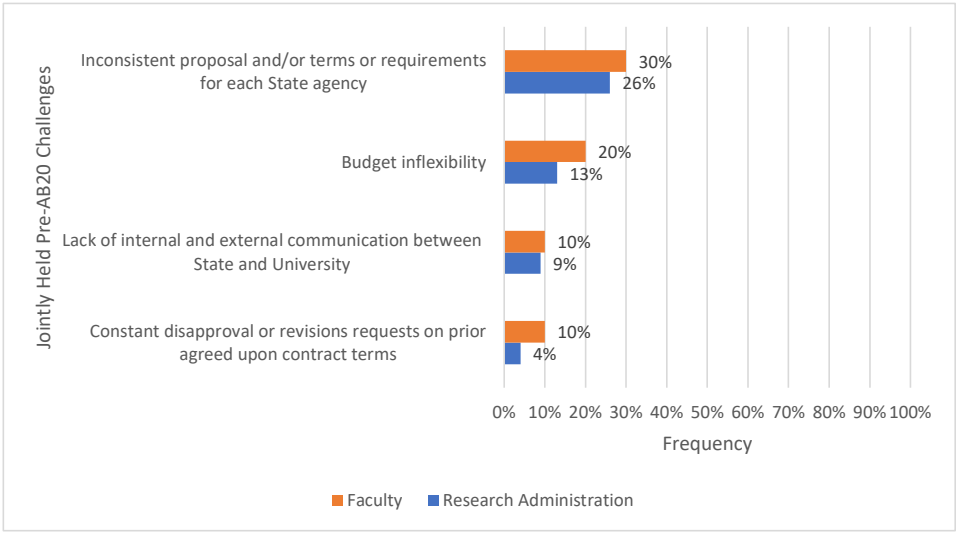
by item of how each group responded: what they had in common (jointly held responses) and what responses they had separately. Research administration staff responses to three of the open-ended questions were notably more varied than were faculty responses, as will be seen in Tables 4-7 for pre-AB20 challenges, critical post-AB20 issues, and AB20 improvements, respectively.

Faculty v. Research Administration Responses by Item

Each interview comprised 7 multi-part questions (Appendix 2) and lasted approximately 20 to 30 minutes. As previously noted, all interviewees had prior research experience with a minimum number of two years of research experience at UC Berkeley.

Pre-AB20 Challenges (Multiple Responses)

Inconsistent proposal and/or contract terms or requirements for each state agency were the predominant pre-AB20 challenge for both faculty and research administration, as displayed in Figure 2. This was followed by budget inflexibility, lack of internal and external communication between the state and the university, and constant disapproval of or revision requests on prior agreed-upon contract terms. Ten percent of faculty respondents deemed the constant disapproval of previously agreed-upon contract terms as problematic, compared to 4% of research administration. Budget inflexibility was also more of a concern for faculty, as were inconsistent proposal terms and communication issues.



Faculty had additional concerns not held by research administration that included uncertainty of how adopting the model agreement would impact their research and uncertainty of what the AB20 CMA process for state contracting would look like.

Table 4. Faculty Pre-AB20 Challenges

Challenge	% Responding
Uncertainty of change when adopting the AB20 CMA process	20%
Uncertainty of processes for State Contracting within the University	10%

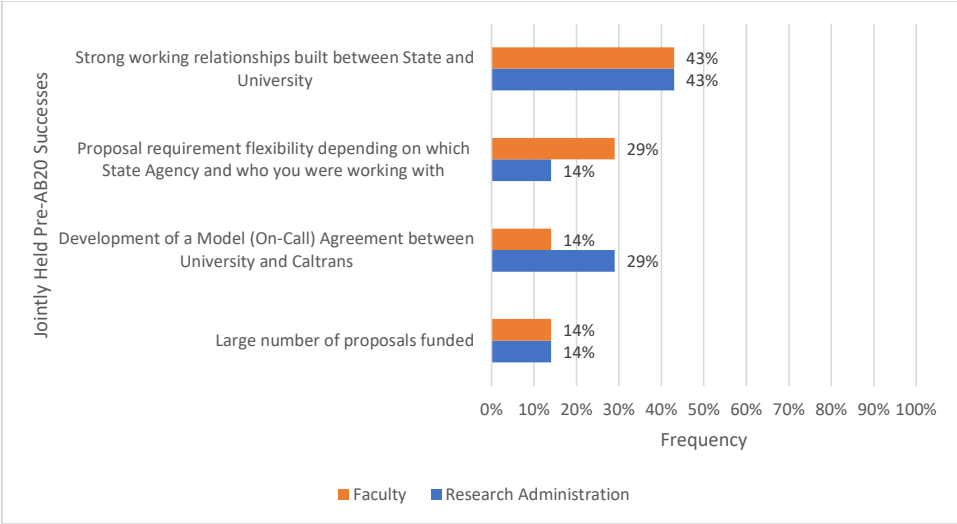
Research administration respondents identified a larger number of issues. Length of negotiation and award times was a concern of 13% of these respondents, as shown in Table 5.

Table 5. Other Research Administration Pre-AB20 Challenges

Challenge	Percentage
Long negotiation and award times	13%
Inconsistent Indirect Costs Rates	9%
Unfavorable contract terms	9%
State agency making proposal or contract changes without communication to University	9%
Disconnect between State Contract Office versus State Program Office	4%
Unsolicated/Informal Request for Proposals	4%

Pre-AB20 Successes (Multiple Responses)

The majority of both respondent groups agreed that the leading pre-AB20 success was the development of strong working relationships created between the state and the university (Figure 3). Both respondent groups agreed in the same proportion on the large number of proposals successfully funded. More faculty expressed agreement with proposal requirement flexibility, whereas research administration were more responsive to the success held by an earlier pre-AB20 working version of the Model (On-Call) Agreement that was piloted between a single state agency (Caltrans) and UC (State of California Department of General Services, 2017). Neither group noted additional successes.



Critical Post-AB20 Issues (Multiple Responses)

Both groups agreed that the most critical post-AB20 issue was "educating the State agencies on how the AB20 CMA process works." "Educating University staff and faculty" as well as "non-standardization of indirect cost rates" were also jointly held issues but not as prominent.

Additionally, research administration respondents noted critical post-AB20 issues that were not shared by faculty. Among these, the inclusion of Exhibit G allowing for alternative model agreement terms was the most prevalent issue, as shown in Table 6.

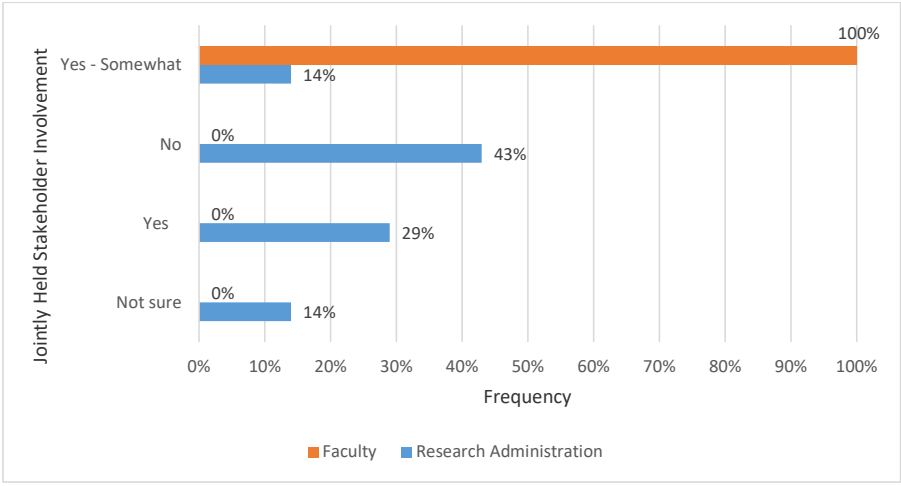
Table 6. Additional Critical Post-AB20 Issues (Research Administration)

Critical Issues Post AB20	**% Responding**
Inclusion of Exhibit G and its allowance for alternate model agreement terms	21%
Federal flowdown on State contracts	7%
Budget inflexibility	7%
Some negotiation still required	7%

Stakeholder Involvement (Single Response)

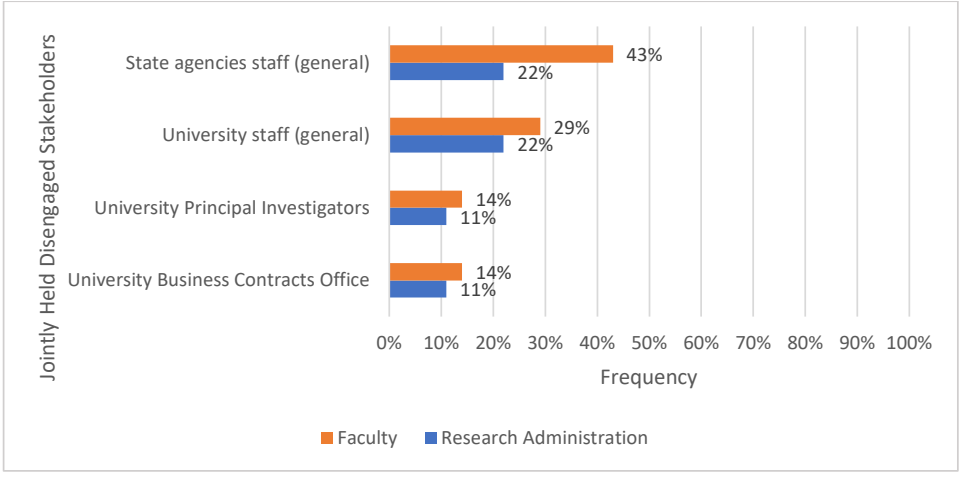
All the faculty respondents reported, with some reservation, that they agreed that the key stakeholders were involved throughout the implementation phases of the AB20 CMA process. Responses from research administration were more mixed, with 29% reporting "Yes" with no

reservations and 14% responding "Yes – Somewhat." Forty-three percent responded "No" to key stakeholder involvement (Figure 4).



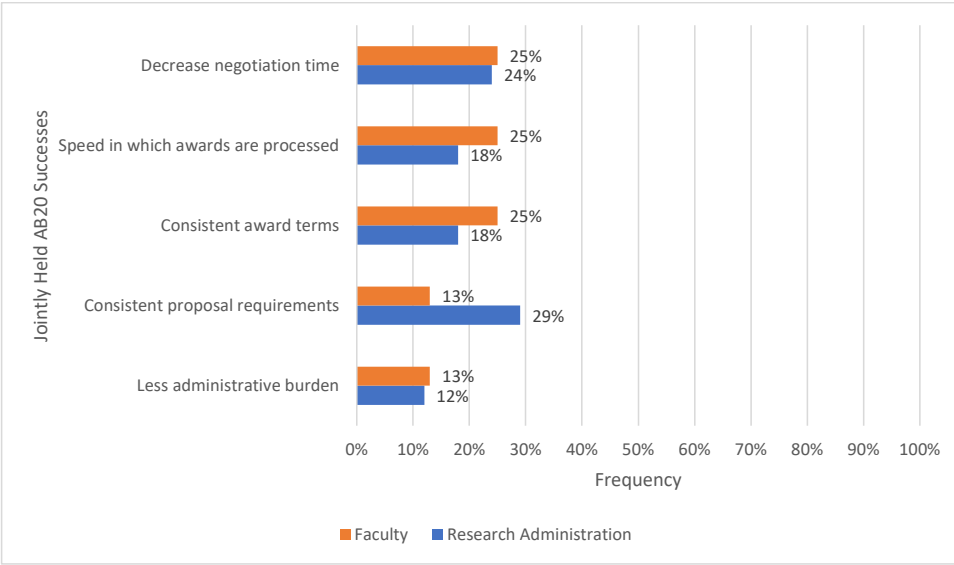
Key Stakeholders Who Were Not Engaged (Multiple Responses)

Research administration respondents were evenly split in their consideration that university staff (general) and state agency staff (general) (22% for each) were not engaged in the AB20 CMA process. Just under half the faculty considered state agency staff (general) to be disengaged as presented in Figure 5. In addition, 11% of research administration also considered the University's intellectual property office to be a key stakeholder that is not currently engaged in the process. Last, 11% of research administration and 22% of faculty reported that they felt all necessary key stakeholders were involved in the AB20 CMA process.



Measures of AB20 Success (Multiple Responses)

When asked if the participant considered the AB20 CMA process a success, the overall interview responses showed far more research administration respondents considered AB20 to be successful 71% (N=5) than faculty 33% (N=1). When the participants were asked "how they would measure success," 25% of faculty responses mentioned the decrease in negotiation time as a top measure of AB20 success; both the speed in which awards were processed and consistent award terms tied as a secondary concern at 11%. Research administration indicated consistent proposal requirements as the top measure of success (29%) followed by decreased negotiation time (24%; see Figure 6).



AB20 CMA Improvements (Multiple Responses)

There were no responses expressed jointly by faculty and research administration on improvement still needed for the AB20 CMA process, with the exception of more education on the AB20 CMA process for both state staff and university staff. Faculty responses were focused evenly on the need for improved turnaround times for executing awards and the need for more education on the proposal and contract process for both state and university staff.

There was a broader range of improvement concerns from research administration, as shown in Table 7. Clearer instruction, more budget consistency, less paperwork, and improved communication from key stakeholders were among the higher responses.

Table 7. Research Administration Responses to AB20 CMA Improvements

Research Administration Responses	**% Responding**
Clearer instruction on proposal requirements	13%
More budget process consistency	13%
Less paperwork for Principal Investigators and Research Analysts	13%
More guidance and communication from key stakeholders	13%
University and State should follow the State University Proposal Administration Manual (SUPAM)	6%
Consistent processes for federal flow down terms	6%
Improvement of invoicing and payment process	6%
More budget flexibility	6%
More education on the AB20 CMA process for both Staff and University staff	6%
More regulation on Exhibit G terms and conditions	6%
Standardizing indirect cost rates	6%

AB20 CMA Recommendations (Multiple Responses)

As with AB20 CMA improvements, there was agreement on only one recommendation between the faculty and research administration: More education on the AB20 CMA process for both state staff and university staff. In general, faculty responses consistently called for improved communication; improved clarity and consistency in the delineated processes, deadlines, and timelines; more training/education; and increased flexibility. These faculty responses are presented in Table 8 below.

Table 8. Faculty Responses to AB20 CMA Recommendations

Faculty Responses	% Responding
Better communication between all parties	11%
Clarity on research contract versus non-research contract processes and requirements	11%
Clearer instruction on proposal requirements	11%
Faster State agency turnaround time for awards	11%
Improve consistency in processes	11%
More consistent State timelines for receiving proposal materials	11%
More education on the AB20 CMA process for both State staff and University staff	11%
More flexibility	11%
University and State should follow the State University Proposal Administration Manual (SUPAM)	11%

Research Administration recommendations in Table 9 focused on more education on the AB20 CMA process (36%), consistency regarding the framework and processes (18%), and more guidance and communication from key stakeholders (18%).

Table 9. Research Administration Responses to AB20 CMA Recommendations

Research Administration Responses	% Responding
More education on the AB20 CMA process for both State staff and University staff	36%
Framework and processes consistency	18%
More guidance and communication from Key Stakeholders	18%
Consistent processes for federal flow down terms	9%
Improvement of invoicing and payment process	9%
Award terms consistency	9%

Discussion of the Findings: Faculty and Research Administration Comparisons

Critical issues since the implementation of AB20 and the CMA centered on education, on its process, and the need for more communication. Budget inflexibility concerns have noticeably shifted from faculty to research administration. The latter staff also noted a concern with the use of the Exhibit G alternative model agreement terms and conditions.

Stakeholder involvement was a potential source for concern, with 29% of research administration agreeing without reservation that stakeholders are involved, and 100% of faculty saying "Yes" with reservations. This area clearly requires clarification and definition. It would provide an opportunity for a more defined AB20 CMA process that ensures the inclusion of all stakeholders, with the concerns of primarily university staff and state agency staff in mind.

The interview data responses regarding the perceived success of AB20 were mixed. Although the majority of research administration agreed that it was successful, faculty largely reported uncertainty. Whereas faculty included decreased negotiation time, consistency of terms, and the increased speed of awards as evidence of success, research administration had mixed responses to these measures.

Broader Implications of the CMA

The impetus for developing and implementing the CMA was the mutual discontent of the California state agencies and the UC and CSU university systems with the status quo. Although the CMA is steeped in the philosophy of the Federal Demonstration Partnership— "finding efficient and effective ways to support research by maximizing resources available for research and minimizing administrative costs" (FDP, 2018)—it is a novel framework providing an all-in-one proposal application and award generation approach. The strengths of the CMA are that, if used as intended, the parties are provided "perfect" information at pre- and post-award stages. The expectations of both parties are known upfront and the resulting agreement can be executed without lengthy negotiation times. Additionally, the modular design of the CMA allows for a controlled customization of its parts without disrupting its core concepts.

The CMA should not be viewed as a California-only innovation; it stands as a model for addressing common challenges in research administration. Academic institutions recognized as state agencies may be particularly interested in its value as a contracting vehicle. For staff at institutions or agencies interested in exploring the CMA framework, they should weigh whether the potential benefits of using this tool are greater than the time, resources, and costs necessary for its success. In making this determination, one must first identify areas of administrative and financial burden with particular funding agencies or potential contractors; consider current working relationships between these groups; gauge the desire on both sides to streamline and work efficiently; and understand the collective stakeholder efforts and support needed to standardize proposal submissions and to reach agreement on terms and conditions—necessitating infrastructural support through complementary, wide-scale organization change. The author would encourage parties to review the aforementioned publicly available draft SUPAM (to be renamed "California Model Agreement Guide" ("CMA Guide" or "CMAG") in 2019/2020). (UCOP, 2016a), which is a road map for how the model agreement process should work and can serve as a valuable resource for those considering the CMA's suitability for their institution or agency.

Recommendations

Based on the research results of both study cohorts, the CMA appeared to be functional in standardizing contract terms and conditions. In August 2017, the CMA underwent its first round of revisions and the following terms and conditions were revised: Liability, Subawards, Invoicing and Payment, Definitions, Confidential Information, and Program Income (UCOP, 2017) based on the concerns of the targeted survey respondents and key stakeholders.

This analysis of UC Berkeley research administrators and faculty interviews highlighted recommendations from both groups, with improvements centered in the following key areas: communication, consistency, flexibility, education, and clarity. The commitment of all parties to the next four goals is critical for the AB20 CMA process to fulfill expectations:

1. Education for all parties involved to use the process model more effectively.
2. Increased communication to improve consistency and clarity regarding definitions and processes.
3. Flexibility on all counts for process improvement.
4. Identification of additional key stakeholders (e.g., various state agencies, procurement, business contracts, and information and technology security and privacy officers) not currently involved, and their participation in streamlining processes and decisions.

The prospect of future AB20 CMA process improvements rests on its primary purpose of streamlining state contracting with academic institutions and also on the partners' ability and willingness to identify gaps, deficiencies, and appropriate solutions. It is equally important that the academic institutions continue to evaluate the myriad of activities they perform for or with state agencies.

The findings of this study point to the need for further research with the goal of determining if a model agreement would work as a paradigm for other state or non-governmental entities. Current economic benefits in the form of faster proposal review times, decreased negotiation time for individual awards, and efficient agreement processing have been reported from the policymakers at the UC and CSU systems. According to UCOP, the next milestone in the AB20 CMA process is to see equal efficiency in the extramural accounting offices. Periodic benchmarking of successes, challenges, and efficiencies from the viewpoints of both an academic institution and a state agency would provide useful information for the research and research administration community. Early discussions have occurred between UCOP, CSU, and academic institutions in other states (notably Virginia and Maryland) that have shown interest in adopting a model agreement process with their state agencies. The AB20 CMA process is a fully developed framework that further research could demonstrate is a robust model for other academic/research institutions and other non-governmental entities outside of California.

Authors' Note

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APPENDIX 1 – EXHIBIT G - NEGOTIATED ALTERNATE UTC TERMS

Exhibit G – Negotiated Alternate UTC Terms (if applicable)

An alternate provision in Exhibit G must clearly identify whether it is replacing, deleting or modifying a provision of Exhibit C – University Terms and Conditions. The Order of Precedence incorporated in Exhibit C clearly identifies that the provisions on Exhibit G take precedence over those in Exhibit C.

While every effort has been made to keep the UTC as universal in its application as possible, there may be unique projects where a given term in the UTC may be inappropriate or inadequate. California Education Code §67327(b) allows for those terms to be changed, but only through the mutual agreement and negotiation of the State agency and the University campus. If a given term in the UTC is to be changed, the change should ***not*** *be noted in Exhibit C, but rather noted separately in Exhibit G.*

APPENDIX 2 – INTERVIEW QUESTIONS

1) Question #1
   a) Name
   b) Job Title
   c) Numbers of years' experience in research and/or research administration

2) Question #2

   From 1 to 10, (10 being very knowledgeable) rate your level of expertise regarding the AB20 State of California Model Agreement (CMA) process?

3) Question #3

   a) Describe the challenges of the State to UC proposal (pre-award) and contract (post-award) process prior to the implementation of AB20 and the CMA.
   b) Describe the successes of the State to UC proposal (pre-award) and contract (post-award) process prior to the implementation of AB20 and the CMA.

4) Question #4

   a) From your experience, what are the critical issues since the implementation of the AB20 CMA process?
   b)Do you think the key stakeholders were effectively engaged as part of the implementation?

5) Question #5

a) Do you consider the AB20 initiative and/or the CMA a success?
b) If so, how would you measure success?

6) Question #6

How can the AB20 CMA process (pre-award and/or post-award) be improved?

7) Question #7

Are there any recommendations that you can provide on how state level contracting can be improved?

Grant Proposal Preparation Readiness: A Glimpse at the Education Level of Higher Education Faculty

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Abstract: *The national need for higher education research has increased over the years with the growth of societal issues. Funding for this research is often acquired through competitive grant proposals due to the lack of internal funding in most universities. The skills required to write the grant are sometimes lacking and represented in current literature as a barrier to attaining grants. Informal grant proposal education often comes in the form of "learn as you go" or through unstandardized online tools or communications. Formal grant proposal education, often presented in undergraduate or graduate education, or through formal grant-funding organization workshops, are often mentioned in current literature as a way to increase the opportunity for a successful grant application. According to the literature, there was a need to determine the current status of grant proposal education. The purpose of this study was to determine whether, and how, higher education faculty members have been educated on how to seek out and apply for external grant funding, and whether or not the area of study they specialize in influences formal versus informal grant proposal writing education for faculty members. According to the results, faculty are educated both formally and informally in various settings, the discipline was significantly related to type of grant proposal education received, and informal education, rather than formal grant proposal preparation, tended to be more successful in number of grants and total dollars attained for this sample of the population.*

Keywords: *Grant Writing; Grant Proposal; Undergraduate Grant Writing Education; Graduate Grant Writing Education; Faculty Preparation*

Current Demographics of Grant Writing

Currently, external grant funding is changing the landscape of both medical and non-medical research and development (NIH, 2016; NSF, 2016). The technological advances and growth in fields such as: (a) engineering; (b) pharmaceuticals; (c) biomedical sciences; and (d) other medical and non-medical fields, are changing how research is performed, as well as the content of the studies. The opportunities for investigators to gain knowledge and information on specific areas and topics have expanded exponentially since the formation of organizations such as the National Science Foundation (NSF), that currently awards the most to campus-based research and development—$45 billion in 2008, to be exact (Bastedo, Altbach, & Gumport, 2016).

The individual topic areas funded vary by foundation, however, the two most prominent grant funding organizations, the National Institutes of Health (NIH) and the NSF, clearly distinguish their areas of study. The NIH promotes the funding of these areas through grants: (a) medical,

both physical and mental; (b) pharmaceuticals; and (c) any health-related area (2016). The NSF broadens the area spectrum to include non-medical research such as: (a) biological sciences; (b) computer and information science; (c) engineering; (d) education; (e) human resources; (f) geosciences; (g) mathematics; (h) chemistry; and (i) physics (2016).

Currently, external federal funding only contributes about 10% of the overall revenue to moderate research higher education institutions, however, at some very prominent research universities external funding can deliver almost 25% of these same revenues. Support in this area is more than necessary to maintain current and future technological advances and increased research efforts to stay at the front of the grant-attaining pack. In 2006, the majority of federal research funding (~60%) went to the natural sciences (including physical sciences), while engineering only received approximately 15% of total funds. Support for the social sciences, between 1975 and 2006, decreased significantly from 7.5% of total funding to 3.6% (Bastedo et al., 2016).

This research project was designed to determine what type of, and how much education grant seekers are receiving, and whether or not that influences their level of success as a grant writer. If attributes that contribute to successful grant proposals can be identified in connection with the preparation of the seekers, the outcome of the time-consuming grant proposal writing process may be improved to result in more awards, and fewer negative outcomes such as non-attainment, as well as the time lost spent preparing the proposal application. As mentioned in previous literature, there are many barriers to writing a successful grant proposal (Boyer & Cockriel, 1998; Monahan, 1993; Walden & Bryan, 2010), however, many of those barriers may be specific to the institutions involved in those studies and may have no effect on other higher education institutions. The current research study specifically focuses on the lack of education barrier that is prevalent in the literature on grant proposal writing. The outcomes of the study attempt to reduce the effects of this barrier on faculty, and remedy the apparent lack of education in grant proposal writing, while increasing the chances for grant attainment.

Advances in technology and economic health are determined through faculty research at many higher education institutions nationwide (Decker, Wimsatt, Trice, & Konstan, 2007). Research funding often comes from external sources beyond the operational budget of the university. The application process for acquiring grants can be troublesome and difficult when faculty lack the skills and ability to apply successfully (Ludlow, 2014). Proposal education is important to the future of research as new and aspiring grant writers enter the faculty ranks with the expectation to learn on-the-job while maintaining and excelling at an already demanding workload (Kleinfelder, Price, & Dake, 2003; Kraus, 2007; Porter, 2007). The difficult nature of attaining external grant funding is shown in the 21% of proposals that were awarded in the 2009 fiscal year, according to the NIH (Dumanis, Ullrich, Washington, & Forcelli, 2013).

The main goal of this study was to determine whether, and how, higher education faculty members have been educated on how to seek out and apply for external grant funding, and whether or not the discipline they specialize in encourages formal versus informal grant proposal writing education for faculty members. By formally educating our new and existing faculty in the skillful art of grant proposal writing, institutions may increase the potential for successful attainment of grants. The purpose of this study was to understand the current climate of higher education grant

writing at a national level by surveying faculty on their education of proposal writing preparation.

Method

This research study employed an embedded research design; this is a mixed-methods approach in which both quantitative (multiple linear regressions and one-way ANOVA) and qualitative data (open-ended questions) were collected simultaneously and analyzed; the qualitative follow-up to the quantitative data for further support and enhancement of the quantitative data is required (Creswell & Plano-Clark, 2011).

There were multiple independent and dependent variables in this study. The independent variables were: (a) formal education on grant proposal preparation; (b) informal education on grant proposal preparation; and (c) the faculty members' discipline. The dependent variables in this study were: (a) proposal preparation level; (b) success; (c) failure; (d) formal education on grant proposal preparation; (e) informal education on grant proposal preparation; (f) amount of funding attained; (g) encouragement/confidence level; and (h) the effect on Sponsored Programs departments.

The participants were full-time, grant-seeking faculty members at Research Highest (R1), Research Higher (R2), or Research Moderate (R3) Doctoral Universities (Carnegie Classification, 2016).

This study employed a census approach to survey the most university faculty possible from fully accredited R1, R2, or R3 doctorate-granting institutions according to the Carnegie Classification and organized regionally through CHEA (2016). The institutions were purposefully selected under three criteria: (1) two institutions were chosen from each of the seven regional accrediting organizations (minus the ACCJC, which does not meet minimum criteria); (2) one institution was public, the other institution was private; and (3) there was an equal number of R1, R2, and R3 universities in the sample. The email addresses of all faculty members of the chosen institutions were manually collected by the researcher via each institution's faculty directory list (approximately 3,700 faculty emails were collected and were sent a link to the survey). The process began by distributing the survey using the Qualtrics survey platform. The survey employed different types of question structures and concluded with an open-ended question/answer section to collect the qualitative portion of the research. This allowed the researcher to gain more insight into the personal experiences of the participants while collecting pertinent information for the study (Baumgartner & Hensley, 2006).

Once Human Subjects Committee approval was gained, a pilot study was conducted using the survey to ensure question clarity and understanding. No major adjustments were made resulting from the pilot study, therefore there was no need to submit any alterations to the Human Subjects Committee. Participants were then contacted via email to complete the survey (all participants were randomly selected from the compiled email lists of included institutions). The final questions in the survey were open-ended and required qualitative analysis. Once the survey was complete, the open-ended portions were extracted and analyzed using a general inductive approach to qualitative data (Thomas, 2006).

The quantitative data were analyzed and reported utilizing descriptive statistics including (a) response frequencies; (b) corresponding percentages; and (c) measures of central tendency. Because this study has multiple independent and dependent variables, such as the relationship between formal and informal education within areas of study, and potentially years of professional teaching experience as well as success versus failure of grant attainment and procurement, the testing of multiple variables was conducted using Linear Regressions (see Figure 1) and a statistical analysis of One-Way ANOVA was performed on formal education being the "norm" in the faculty members' discipline, and in which discipline the faculty member currently taught.

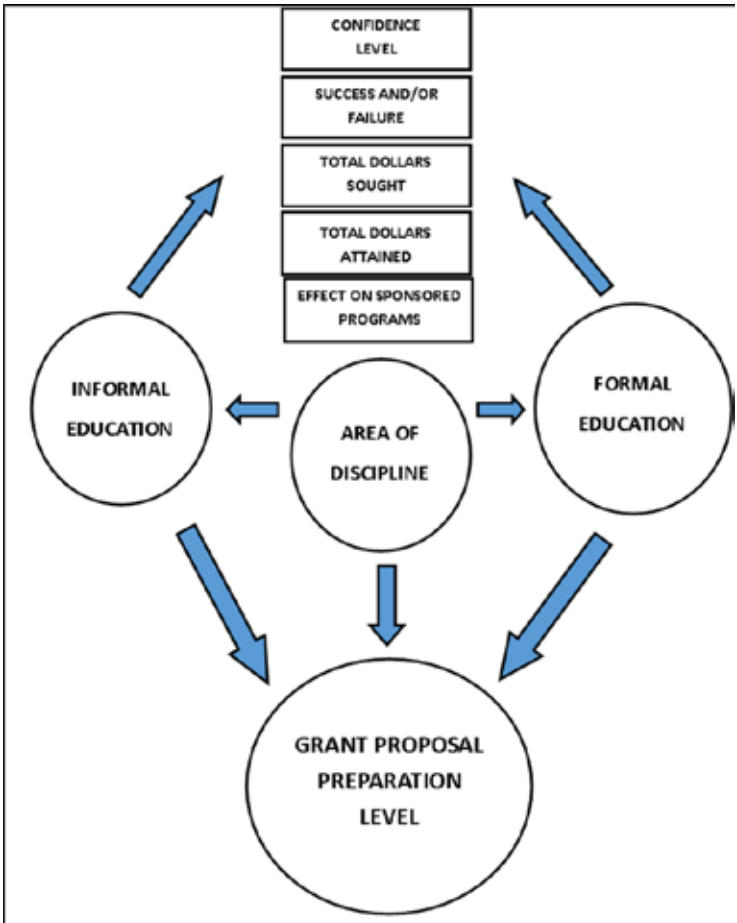

Figure 1: Relationships of Independent and Dependent Variables

These statistical tests were used to determine whether formal or informal grant writing education had an effect on perceived success or failure, or additionally, other dependent variables of the study. The respondent's discipline was also used as a variable to determine whether the relationship existed between formal or informal training in specific disciplines within higher education institutions. Multiple regression models were designed to measure the effects of the independent variables in predicting the dependent variables (e.g., confidence and preparation level).

The qualitative analysis was based on the narrative data extracted from the open-ended question section of the survey. The analysis of the qualitative data followed the General Inductive Approach described by Thomas (2006). The data were collected verbatim and read by multiple researchers (triangulation) to develop categories and themes using open coding. The data were re-read and categories were assigned to all data units (Thomas, 2006). Categories were organized into key themes and subthemes. The key themes, and the connections among them to support the quantitative data, were reported and supported using appropriate quotations from the transcribed data. The themes and connections were used to address, and to help answer, the research questions.

The major delimitation to this study was the use of only full time, grant-seeking faculty members. The inclusion of adjunct, or part-time, faculty or other non-faculty grant-seeking individuals could have resulted in a different outcome, or potentially a much higher response rate, increasing the ability to generalize to the overall population. The population not included in this study may also have had important contributions to grant proposal education techniques as this topic expands on a national level.

Results

Of the respondents who completed the survey, 47.4% were female (n = 18), while 52.6% were male (n = 20). Faculty rank resulted in the following distribution: (a) Assistant Professor, 18.4% (n = 7); (b) Associate Professor, 31.6% (n = 12); and (c) Professor, 50.0% (n = 19). When asked if the participating faculty member had a primarily "clinical" or "research"-related component to the faculty appointment, 39.5% responded "no" (n = 15); the remainder of the sample, 60.5% (n = 23) responded "yes, research." No participants in this study responded "yes, clinical". The researcher inquired about tenure status. Only two of the 38 participants (5.2%) responded to the non-tenure track option, while 7 participants (18.4%) were currently on the tenure-track at their respective universities. The majority of the responding participants were already tenured faculty members (76.3%; n = 29) (see Table 1).

Multiple Regression Analyses

The regression analyses indicated 43 statistically significant results ($p \leq .10$), and over 200 insignificant relationships between independent and dependent variables for this study. According to Borg and Gall (1989), most educational studies use $p \leq .05$, however "exploratory studies may use an accepted value of $\leq .10$" (p. 351). In regression analysis, the regression model strives to produce a high R-squared value paired with a significant p value ($p \leq .10$). This low p value / high R2 combination indicates that changes in the predictors are related to changes in

the response variable and that your model explains a lot of the response variability (Creswell & Plano-Clark, 2011). The results of the multiple linear regressions showed significant relationships among area of education regressed on: (a) conducting original research as a requirement during undergraduate education (R2 = .134, p = .014); (b) formal education being the "norm" in the faculty members' discipline (R2 = .179, p = .005); (c) formal workshops being most helpful to faculty members when writing a grant proposal (R2 = .027, p = .169); (d) informal education through "learn as you go" or "trial and error" processes making a faculty member feel confident about grant proposal preparation (R2 = .122, p = .018); and (e) informal situations being most helpful when preparing grant proposals (R2 = .141, p = .012). From these results, one can conclude that the discipline has a significant relationship to how the faculty member is educated (whether formally or informally), and what they believe and feel is most helpful to them in grant proposal preparation situations.

AThe results of the multiple linear regressions of formal education factors showed various statistically significant relationships. Among them, formal education of preparing a mock grant proposal during the master's degree program regressed on how often faculty members look for grants to apply to (R2 = -.088, p = .079). As far as applying for the actual grants, significance was found when faculty members were: (a) educated during their undergraduate education through actual grant proposal preparation (R2 = .265, p = .003); (b) educated during their doctoral program by conducting original research (R2 = -.010, p = .071); and (c) when the faculty member had to write a proposal for completion of the terminal degree (R2 = -.010, p = .064). This demonstrates that education in a formal setting may promote a faculty member to apply for more grants than those not educated formally.

Regarding the confidence level of the faculty members (participants), the most significant results arise from many of the formal education factors. Faculty members gained a high level of confidence for preparing grant proposals when they were prepared formally through: (a) undergraduate education when grant preparation was part of the assignment (R2 = .284, p = .086); (b) undergraduate education when involved in a quantitative research class (R2 = .284, p = .039); (c) master's level education when they were required to conduct original research (R2 = .205, p = .028); (d) master's level quantitative, as well as qualitative research courses (R2 = .274, p = .074, p = .063, respectively); (e) graduate level courses devoted to grant proposal preparation (R2 = .220, p = .090); (f) doctoral level courses in which mock proposals were a requirement (R2 =.205, p = .027); and the most common result, (g) when formal education was the "norm" in that faculty member's discipline (R2 =.274, p = .006). The results of the regressions on formal education factors show the importance related to how confident the participants were about preparing grant proposals.

Funding source seminars provided by the NIH, NSF, USDA, NEH, etc. also allowed faculty members to experience confidence when they were formally educated previously through: (a) undergraduate courses that involved mock grant proposal preparation (R2 =.220, p = .043); (b) a terminal degree requirement to prepare a grant proposal (R2 =.220, p = .090) and (c) when they previously attended a helpful formal seminar provided by those same funding sources (e.g., NIH, NSF, USDA, NEH) (R2 =.220, p = .057).

Finally, significance was demonstrated for the encouragement level of the faculty members due to a funding source seminar provided by the NIH, NSF, USDA, NEH, etc. when: (a) faculty members were educated in an undergraduate quantitative research course (R2 =.255, p = .060); (b) formal education was the "norm" in the faculty members' discipline (R2 =.255, p = .025) and (c) when they previously attended a helpful formal seminar by those same funding sources (e.g., NIH, NSF, USDA, NEH) (R2 =.255, p = .078).

Informal education factors were also regressed against various grant proposal preparation factors. No significant results were displayed among any of the informal education factors and grant proposal preparation level of the faculty members, however, there was a significant relationship with being informally educated and the number of grants applied for, as well as total dollars attained through external grant writing (R2 = .284, p = .004, R2 = .267, p = .006, respectively).

Regarding the confidence level of the participants of this study, participants who experienced grant writing education during their graduate degree showed a significant relationship with informal situations being quite helpful to them in preparing an actual grant proposal (R2 =.039, p = .066). Another significant statistic emerged when informal situations were helpful to those who had experience with funding source seminars (e.g., NIH, NSF, USDA, NEH) (R2 =.050, p = .071). This combination of experiences (informal and formal) was pertinent throughout the open-ended response section of the survey.

Regarding the relationship between Sponsored Programs offices and the effect, if any, they had on informal education factors, demonstrated very little statistical significance; except for the "learn as you go" or "trial and error" factor. This element showed significance when paired with faculty members who considered grant writing assistance through the Sponsored Programs office to be helpful (R2 =.076, p = .043).

According to the qualitative portion of this study, there were five major themes with various supporting subthemes, according to the triangulation and development of themes through the process of General Inductive Theory. The major themes included: (1) formal education opportunities for grant proposal preparation; (2) informal education opportunities for grant proposal preparation; (3) motivators to prepare grant proposals for research purposes; (4) barriers to prepare grant proposals for research purposes; and (5) types of grants sought by faculty members.

Discussion

Overall, the results of this study determined that faculty are educated both formally and informally in various settings, the discipline was significantly related to type of grant proposal education received, and informal education, rather than formal grant proposal preparation, tended to be more successful in number of grants and total dollars attained for this sample of the population. The following questions guided this study: (1) To what extent are faculty members educated on the grant writing process?; (2) Does formal grant education contribute to the success level of grant acquisition in terms of the numbers of grants submitted and received?; (3) Does the discipline influence whether faculty members are formally or informally educated on grant

writing?; and (4) Does formal or informal education on grant proposal writing affect the amount of funding faculty seek out and attain?

To what extent are faculty members educated on the grant writing process?

According to the results of this study, faculty members, depending on discipline, were educated both formally and informally, through various undergraduate and graduate courses, as well as through funding source seminars provided by the NIH, NSF, USDA, NEH, etc., "learn as you go," "trial and error," and collaborative situations. Neither type of education was determined to be better or more beneficial than the other, and in some instances, both were mentioned together. According to the responses, faculty in the natural sciences were often more formally educated than those in other disciplines, but responses showed varying levels of education among all disciplines.

The descriptive statistics and the qualitative, or open-ended portion of this study, showed that many of the faculty members were older and had either not had the opportunity to experience formal grant proposal education through their undergraduate or graduate degrees and gained experience by learning on the job as grant writing became more common in higher education. Some participants described undergraduate and graduate education experiences through different courses and/or requirements within their academic careers. The findings of the current study contradict the findings of previous literature (Kraus, 2007; Medina-Walpole, Barker, & Katz, 2004).

Table 1. Demographic Results of Faculty Status (n = 38)

	Frequency	**Percentage**
Female	18	47.4
Male	20	52.6
Faculty Rank		
Assistant Professor	7	18.4
Associate Professor	12	31.6
Professor	19	50.0
Primarily a Clinical or Research Appointment		
No	15	39.5
Yes, Research	23	60.5
Tenure Status		
Tenured	29	76.3
Tenure Track	7	18.4
Non-tenure Track	2	5.3

Does formal grant education contribute to the success level of grant acquisition in terms of the numbers of grants submitted and received?

There was no significant or outstanding relationship, according to the statistical analysis, that determined formal education as a more successful route to grants submitted or received. In some instances, in fact, according to this research study and the statistical analysis of attainment and total dollars attained, informally educated faculty members were just as, if not more successful than their formally educated counterparts.

Does the discipline influence whether faculty members are formally or informally educated on grant writing?

In simple terms, yes, the discipline had a significant relationship to the type of education received by the faculty member in this study. According to the one-way ANOVA performed ($p = .038$), faculty members who resided in the "hard sciences" (e.g., biochemistry, biological sciences, ecology, health professions, neuroscience, physiology, and animal science) considered being formally educated the "norm" in their disciplines. According to Arlitsch (2013), "Grant funding supports universities and academic faculty, particularly in the hard sciences..." (p. 370). While faculty in other disciplines do pursue external grants and strive for more formal education, the idea that faculty in the hard sciences are more commonly educated in grant proposal preparation is not a newfound concept (Blankenship, Jones, & Lovett, 2010; Drotar et al., 2015; Seifried, Walker, Forman, & Andrew, 2015).

Does formal or informal education on grant proposal writing affect the amount of funding faculty seek out and attain?

Formal education factors showed no significant relationship with how often grant opportunities were sought out by the participants. However, the formal factor of grant writing education incorporated into a master's program through mock grant proposal preparation did show significance with seeking out grant opportunities. Receiving education during the undergraduate program through mock grant proposals showed a strong relationship with actually applying to the grant opportunities sought out by faculty members. This shows that formal education may help better prepare the grant seeker to actually submit a grant proposal for external funding. Statistical significance was demonstrated through regressing grant proposal education during the doctoral program through conducting original research and writing a grant proposal as part of the terminal degree when regressed on how many external grants the participant has applied for since becoming a full-time faculty member. No significance appeared in the total dollar amount attained for any of the formal education factors.

Regarding the informal education factors of "learn as you go" or "trial and error" learning situations, significance was demonstrated when grants were sought out, applied for, and/or attained. As far as total dollar amount attained was concerned, significance was seen in the "learn as you go" or "trial and error" situation. No current literature has explored this concept, nor represents this finding; it is an original result and is unique to this research study.

Recommendations

Due to the results of this study, there were some recommendations for future researchers when it comes to exploring the barrier of lack of education to grant proposal preparation. Including all levels of faculty in the study, not just those with a grant-seeking component to their scholarship duties, may have resulted in a higher response rate (= 1.05%) with more widely varying experiences on grant proposal preparation. Future research on grant proposal preparation should examine all faculty levels and other grant-seeking (non-faculty) departments in order to produce a wider variety of responses. Viewing the grant proposal process from the administrative perspective and how to best organize faculty positions and responsibilities should also be explored in further detail to promote the seeking and attainment of grant funding.

The quick glimpse at Sponsored Programs offices that this study provided could be explored in more detail, as well. Some of the responses of participants demonstrated the assistance provided by Sponsored Programs offices for grant proposal preparation as quite lack-luster. By exploring how much these offices actually assist (or rather, do not assist) faculty members at the university level, potential increases in the support provided to grant-seekers to increase research activity could be attained. This increase in support may also assist more faculty in exploring the opportunity to prepare a grant proposal for external funding, thereby increasing their professional portfolios, as well as increasing the funding in their respective department and university. Interaction from the Sponsored Programs offices in universities, especially incorporated into the classroom, could potentially increase the seeking and applying components to grant proposal writing.

Conclusion

As a result of this study and consistent with the literature (Blankenship et al., 2010; Cole, Inada, Smith, & Haaf, 2013; Gaugler, 2004; Kleinfelder et al., 2013; Reed, Kern, Levine, & Wright, 2005), it is recommended that faculty consider including grant proposal opportunities in their curricula, especially at the Masters and Doctoral levels, to better prepare future faculty. While formal education can assist in preparing the faculty member for the grant application process, the timing and availability of funds, dependent upon the discipline, should also be taken into consideration; being prepared is important, but if money is not available, grant attainment becomes quite difficult. Faculty members who can potentially achieve reviewer status (of grant proposals) could gain quite a bit of experience on the grant application process for future research of their own.

Last, the remaining barriers identified by this and other research studies could use more exploration, as well (Monahan, 1993; Dooley, 1995; Boyer & Cockriel, 1998; Walden & Bryan, 2010). These barriers include: (a) a lack of time due to teaching, advising, service, and other aspects of scholarly duties; (b) a lack of advance notice of available grants to pursue; (c) seeking external funding sources; (d) preparing proposals and budgets; (e) getting necessary approvals; and (f) dealing with campus business staff (distribution and management of funds). Motivators are also very important to focus on to continue the process of seeking and applying for grants. Yet, if the barriers could potentially be reduced and/or eliminated in some universities, grant proposal preparation may possibly increase along with research efforts by all levels of faculty.

Authors' Notes

Dr. Kristin M. Shuman is currently employed as an Assistant Professor of Exercise Science at Concordia University Ann Arbor. This manuscript was derived from the author's Doctoral Dissertation which was successfully presented and defended in April 2017 at Idaho State University in Pocatello, Idaho.

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Appendix 1. Survey Questions and Response Options

1. Gender
   Female
   Male

2. Faculty Rank
   Assistant Professor
   Associate Professor
   Professor
   Other: Please specify: _____

3. Is your faculty appointment primarily Clinical or Research?
   No
   Yes, Clinical
   Yes, Research

4. Tenure Status
   Tenured
   Tenure-Track
   Non-Tenure Track

5. Do you have a grant seeking component to your workload? How many hours are required of your overall workload?
   Yes
   No
   # of required hours: _____

6. Graduate degrees earned? Check all that apply.
   Doctorate (EdD) Discipline: _____
   Doctorate (PhD) Discipline: _____
   Doctorate (other) Specify Degree and Discipline: _____
   Master's Degree and Discipline: _____
   Other: Please Specify Degree and Discipline: _____

7. Total professional experience as a faculty member
   0 - ≤2 years
   >2 - ≤5 years
   >5 - ≤10 years
   >10+ years

8. Discipline of Major Faculty Appointment
   Agriculture
   Architecture and Related Programs
   Biological Sciences
   Business
   Computer and Information Sciences
   Education
   Engineering
   Fine Arts & Humanities
   Health Professions
   Law
   Physical Sciences
   Social Sciences
   Other: Please list _____

9. How many external grants have you applied for since you became a full-time faculty member?
   0
   1-5
   6-10
   11-20
   20+

10. How many external grants have you been awarded since you became a full-time faculty member?
   0
   1-5
   6-10
   11-20
   20+

11. How much total money have you acquired through successful external grant applications?
   $1 - $10,000
   $10,001 - $100,000
   $100,001 - $500,000
   $500,001 - $1,000,000
   $1,000,001+

12. How often do you look for grants to apply for?
   Never
   Daily
   Weekly
   Monthly
   Annually

13. How often do you apply for the grants you find?
    Never
    Occasionally
    Always

Below are statements with which you may agree or disagree. Using the five point scale below, please indicate your level of agreement with each item.

1 = strongly agree
2 = agree
3 = neither agree or disagree
4 = disagree
5 = strongly disagree
n/a = not applicable

1. During my undergraduate education, it was required for students to conduct original research in my resultant degree field.	①②③④⑤ n/a
2. Grant writing education was incorporated into my undergraduate education through direct assignments focused on preparing a mock grant proposal.	①②③④⑤ n/a
3. Grant writing education was incorporated into my undergraduate education through research training (quantitative) to assist in preparing a grant proposal.	①②③④⑤ n/a
4. Grant writing education was incorporated into my undergraduate education through research training (qualitative) to assist in preparing a grant proposal.	①②③④⑤ n/a
5. During my graduate education (Master's), it was required for students to conduct original research in my resultant degree field.	①②③④⑤ n/a
6. Grant writing education was incorporated into my graduate education (Master's) through direct assignments focused on preparing a mock grant proposal.	①②③④⑤ n/a

7. Grant writing education was incorporated into my graduate education (Master's) through research training (quantitative) to assist in preparing a grant proposal.	①②③④⑤ n/a
8. Grant writing education was incorporated into my graduate education (Master's) through research training (qualitative) to assist in preparing a grant proposal.	①②③④⑤ n/a
9. Grant writing education was incorporated into my graduate education (Doctorate) through direct assignments focused on preparing a mock grant proposal.	①②③④⑤ n/a
10. Grant writing education was incorporated into my graduate education (Doctorate) through research training (quantitative) to assist in preparing a grant proposal.	①②③④⑤ n/a
11. Grant writing education was incorporated into my graduate education (Doctorate) through research training (qualitative) to assist in preparing a grant proposal.	①②③④⑤ n/a
12. During my graduate education (Doctorate), it was required for students to conduct original research in my resultant degree field.	①②③④⑤ n/a

13. Writing a grant proposal was part of my terminal degree.	①②③④⑤ n/a
14. Education provided in an undergraduate grant writing course has helped me feel confident when writing a grant proposal.	①②③④⑤ n/a
15. Education provided in a graduate grant writing course has helped me feel confident when writing a grant proposal.	①②③④⑤ n/a
16. Education provided in an undergraduate quantitative research course has helped me feel confident when writing a grant proposal.	①②③④⑤ n/a
17. Education provided in a graduate quantitative research course has helped me feel confident when writing a grant proposal.	①②③④⑤ n/a
18. Education provided in an undergraduate qualitative research course has helped me feel confident when writing a grant proposal.	①②③④⑤ n/a
19. Education provided in a graduate qualitative research course has helped me feel confident when writing a grant proposal.	①②③④⑤ n/a
20. A funding source seminar/workshop i.e. NIH, NSF, USDA, NEH, etc. has helped me feel confident when writing a grant proposal.	①②③④⑤ n/a
21. Experiencing grant proposal writing education (i.e. education in undergrad/grad education) encouraged me to apply for an external grant.	①②③④⑤ n/a
22. Experiencing grant writing education (i.e. an educational seminar/workshop from an external funding source i.e. NIH, NSF, USDA, NEH, etc.) would encourage me to apply for an external grant.	①②③④⑤ n/a
23. Being formally educated in grant writing is the norm in my area of discipline.	①②③④⑤ n/a
24. Informal grant writing education (i.e. "learn as you go" or "trial and error" through personal or collaborative efforts among colleagues) has made me feel confident when writing a grant proposal.	①②③④⑤ n/a

25. Experiencing informal grant writing education (i.e. "learn as you go", "trial and error") would encourage me to apply for an external grant.	①②③④⑤ n/a
26. Being informally educated in grant writing is the norm in my area of discipline.	①②③④⑤ n/a
27. My university offers grant writing assistance programs through the Sponsored Programs/Research Development office.	①②③④⑤ n/a
28. The grant writing assistance programs through the Sponsored Programs/Research Development office are very helpful.	①②③④⑤ n/a
29. Formal workshops are most helpful to me when I write a grant proposal.	①②③④⑤ n/a
30. Informal situations are most helpful to me when I write a grant proposal.	①②③④⑤ n/a

Open-Ended Questions

1. What types of grant writing education have you participated in (internal, external, competitive, non-competitive)? What value did it have, if any?
2. When applying for an external grant, do you consider the type of grant (non-competitive vs. peer-reviewed/juried) before preparing a proposal? Is one more attractive than the others? Why or why not?
3. How many grants have you received as a student? How many grants have you received as a faculty member?
4. What are the barriers, if any, that prevent you from preparing external grant proposals? What are the motivators, if any, that promote you to prepare external grant proposals?
5. Do you feel prepared from your undergraduate and/or graduate education to create a grant proposal for external funding? Why or why not?
6. How do you define "success" in regard to writing grant proposals?
7. How could you have been better prepared for the expectation of grant proposal writing at the university level?
8. Would you like more opportunities to formally learn how to prepare a grant proposal? If so, what types of opportunities would you benefit from most?
9. What additional comments do you have regarding grant proposal preparation?

Catalyzing Clusters of Research Excellence: An Institutional Case Study

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Abstract: *Over the last decade, a wealth of empirical evidence has accumulated describing the merits of team-based, collaborative, and interdisciplinary research, including: increased productivity among researchers, greater citation impact, increased multi-sector engagement, and the generation of novel solutions to grand challenges. Funding agencies have accordingly increased the frequency of large-scale collaborative and partnered grant opportunities. However, institutional structures and processes can inadvertently limit team-based interdisciplinary research at universities. Research Clusters (which we define as interdisciplinary networks of researchers who organize to solve key challenges facing society) provide a flexible and adaptable mechanism to enable collaborative research across internal and external institutional boundaries. Versions of research clusters are now commonly a central theme in research strategic plans at universities, but there remain very few resources available to research administrators and leadership to support the development of their internal strategies and processes to support research clusters. Here, we describe our experiences developing and implementing initiatives to catalyze clusters of research excellence at the institutional level and reflect on early successes and challenges. We share our framework for identifying, evaluating, and catalyzing research clusters and provide specific examples of internal processes and analytical tools that we have developed.*

Keywords: *Institutional Strategy; Interdisciplinary Research; Research Clusters; Research Excellence; Research Facilitation*

Introduction

Interdisciplinary collaboration among researchers generally increases productivity, generates higher impact work (Wutchy, Jones, & Uzzi, 2007), and results in the training of more collaborative researchers (Hampton & Parker, 2011). In light of the mounting evidence of the benefits of collaborative research (e.g., Adler & Stewart, 2010; Beaver, 2004; Jones, Wutchy, & Uzzi, 2008; Lee & Bozeman, 2005), it is not surprising that collaboration is increasing across all research disciplines (Jones et al., 2008; Wutchy et al., 2007).

Funding agencies and programs are following suit: because research clusters and teams generate high-impact knowledge and research that contribute to solving big open questions, the last 5-10 years has seen an increase in big-ticket research opportunities for team-science (Halliwell & Smith, 2011). Canadian examples include: Canada First Research Excellence Fund ($1.25B CAD since 2012; CFREF, 2017), Networks of Centres of Excellence ($560M CAD since 2012; NCE, 2017), Canada Foundation for Innovation (CFI team grants, $1B CAD since 2012; CFI, 2017), and dozens of intermediary team/partnership grants through other federal programs. Similar programs are found globally, e.g., NSF Engineering Research Centers (US), Centres of Research Excellence (Australia), and Horizon 2020 (European Union). In all of these granting programs, foundational components of the evaluation and selection process are the level of excellence of the individuals involved (i.e., traditional research metrics) and the strength and cohesion of the team (e.g., proven track-record of the group's ability to work together as a team). The Canadian NCE program even requires applicants to explicitly justify the synergies of the team that enable the award to have greater impacts than equivalent grants to individual researchers.

The role of institutions in these large-scale programs often seems to be reduced to ensuring compliance, reporting, and providing matched funding for large team grants in the form of cash (e.g., Department, Faculty, and Central funds) and in-kind (administrative and reporting support, space, etc.) contributions. However, for the administration and leadership at an institution to enable faculty to facilitate the creation of truly transformative research programs and therefore to be more successful in these competitions, we need to proactively consider how to develop institutional practices that encourage the development and growth of such research clusters even before particular funding opportunities are known.

A recent review of the benefits for, and risks to, individual researchers participating in team grants (Canadian Academy of Health Sciences [CAHS], 2017) called for institutions to increase their support and recognition of team science participants. Indeed, establishing and supporting clusters of research excellence now commonly appears in institutional research strategic plans, in one form or another. However, despite a wealth of literature providing researchers with motivation to participate in team science and examples of previous successes (e.g., Adler & Stewart, 2010; Boardman & Ponomariov, 2014; Guise, Winter, Fiore, Regensteiner, & Nagel, 2017; Reichman, 2004; Stokols, Misra, Moser, Hall, & Taylor, 2008), minimal guidance is available to institutions on developing policies and processes to support the development of interdisciplinary clusters of research excellence.

Over the last three years, we have piloted institutional support of the development of research clusters. In this paper, we suggest a framework for identifying, evaluating, and catalyzing clusters of research excellence. We describe and justify our approach, providing specific examples of internal processes and analytical tools that we have implemented and end by discussing challenges and early successes of the program, summarizing lessons learned. We hope that this paper will be useful for other institutions and will spark further dialogue about the roles that institutional administration and leadership can play in supporting research clusters.

Planning support for the development of research clusters

Collaboration is a central theme in our institutional strategic plan (University of British Columbia, 2018) and enabling the development of collaborative research clusters is an identified core strategy. With this goal in mind, we set out to first understand baseline patterns in collaboration in interdisciplinary areas at the University, and then to identify any existing institutional barriers restricting collaborative approaches to research. In this section, we describe our approaches to those challenges and how these exercises were critical in designing our collaborative research support program.

Scoping baseline collaboration in interdisciplinary research areas

In larger institutions with thousands of faculty members, a lack of collaborative research initiatives might simply reflect a lack of awareness of other researchers working on related topics in other departments. To assess this issue, we analyzed the extent of pre-existing collaborations among researchers working on related topics and explored whether or not research clusters would develop organically around interdisciplinary topics following strategically designed networking opportunities. We chose four interdisciplinary research areas that had been identified by a recently established cross-faculty consortium whose mandate is to coordinate interdisciplinary health research and education: Indigenous Health, Mental Health, Ageing, and Diabetes: Lifestyle & Biology.

First, we needed to identify researchers across the institution that could meaningfully contribute to research in the four interdisciplinary areas. We started by devising a series of descriptive terms that could be searched through our internal researcher indexing system to identify an initial list of researchers working in each area. For instance, in the case of mental health: "*mental*" OR "*psychological*" OR "*brain*" AND "*illness*" OR "*health*" OR "*wellbeing*" OR "*wellness*"; "*psychology*"; "*psychiatry*". Examples of systems and databases to search when a centralized search function is not available include: institutional researcher webpages, supervisory records for research trainees, research funding and application tracking systems, ethics application databases, etc. Recognizing that even the most thorough search process misses key researchers (e.g., recent hires; researchers who use only technical words to describe their work; clinicians; digital ghosts), we distributed the draft list of potential researchers broadly among unit leaders to help identify any additional researchers.

With a revised list of researchers relevant to each cluster, we were then able to gather evidence of existing research excellence and collaborative trends in each of the interdisciplinary areas, instead of by more traditional organizational units (i.e., faculty, department). To assess research activity and impact, we aggregated traditional research metrics on the individuals (e.g., research funding, major awards, publications, citation impact, media attention/reach). To inform which and how many researchers in the interdisciplinary areas had previously collaborated and whether patterns of collaboration were associated with institutional divisions (i.e., collaborations not happening across faculties), we assessed co-publications among the researchers identified. We used co-publications as a convenient proxy for collaboration because pairwise collaboration data can be mined freely from Web of Science or through third party paid software. However, it is

important to note that publication metadata is not likely an accurate proxy in all fields and will be most accurate in fields where publications are the major research output. In circumstances where publications are not the primary research output, collaboration mapping exercises should be supplemented with appropriate data (e.g., co-supervised students, co-PI status on grants, or co-produced exhibits or performances).

In the four interdisciplinary research areas that we surveyed, we found that 27-58% of the researchers identified had never collaborated with another researcher on the list (Table 1). Of the pre-existing collaborative links among researchers, only a minority (12-43%) crossed Faculty boundaries (Table 1). To elucidate the processes responsible for observed patterns in collaboration, explore whether significant interest in collaborative research existed, and solicit input on what sorts of institutional support would be needed to catalyze further collaborations, we invited all of the researchers identified to a collaborative research workshop for each of the four interdisciplinary areas. At these working sessions (attended by 22-55% of the researchers invited), we provided networking opportunities for researchers across the University, presented our baseline analyses of collaboration and research activities in the given research area, and discussed opportunities for and barriers inhibiting further collaborations. Participants unanimously expressed excitement towards new collaborations but emphasized that central support was needed to further develop collaborative research initiatives, in the form of seed grants, strategy support, partnership development, and government/community engagement.

Table 1. Scoping Internal Collaborations In Four Sample Interdisciplinary Research Areas

Interdisciplinary research theme	Indigenous Health	Mental Health	Ageing	Diabetes: Lifestyle & Biology
Researchers identified	110	80	82	166
% without existing UBC collaborations	27%	58%	32%	50%
% UBC collaborations across Faculties	12%	37%	43%	31%
% participating in research exchange	55%	37%	22%	24%

Designing support to increase collaboration

Our initial scoping of collaborative research activity in the four interdisciplinary research themes revealed that many researchers had already collaborated in these interdisciplinary fields in the absence of formal institutional initiatives, but also highlighted immense opportunity to support additional collaborations within and across faculties. To decide how best to support the development of collaborative research groups, we supplemented the feedback from the four working sessions with broader consultation within our research community (researchers and leadership across faculties) and an environmental scan of support programs at other institutions.

Our initial environmental scan of comparator universities found that institutions vary in their definition of interdisciplinary research clusters and consequently in their pathways to identifying and supporting institutionally recognized clusters of research excellence. Most universities define and organize research clusters by disciplines of institutional strength, determined internally or externally (e.g., Simon Fraser University, 2018), while others organize around institutionally identified *Grand Challenges* (e.g., University of California Los Angeles, 2018) or economic sectors (e.g., University of Toronto, 2018). However, we did not discover a single instance where University support for collaborative research was targeted at providing developmental support for grassroots initiatives and self-organizing research clusters. In spite of this apparent gap, our research community strongly advocated for such an approach and in the absence of model support programs to emulate, we created a novel support program.

Through on-going engagement with our internal research community, we settled on a more general (and discipline-agnostic) definition of research clusters as interdisciplinary networks of researchers who organize to solve challenges facing society. Researchers comprising clusters should represent established leaders and rising stars in their areas of expertise working closely together as a unit on complex problems that often transcend traditional departmental, institutional, or disciplinary boundaries. To develop structures and processes that would support the development of such broadly defined research clusters, we described cluster support through a tiered development framework (Figure 1).

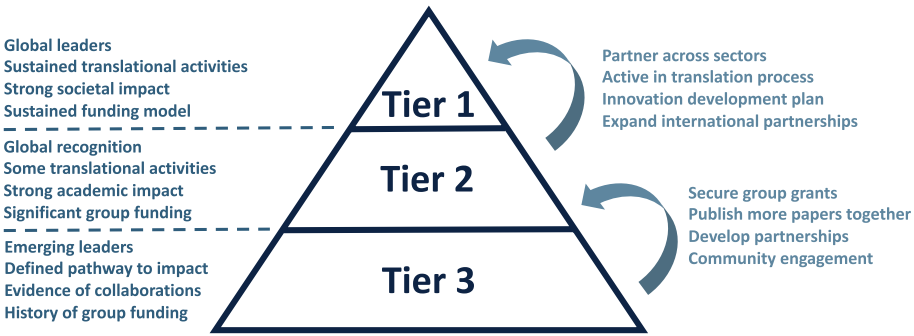

Figure 1. Conceptual tiered framework for development of research teams from emerging clusters to global leaders, showing (on the left) the characteristics of clusters at various developmental stages and (on the right) the catalytic activities needed to continue on a trajectory to becoming a world-leading research cluster. Our research cluster support initiative was designed to enable these catalytic activities.

We first identified characteristics for each tier that should remain true for clusters working on any interdisciplinary research theme and the catalytic activities that would be needed to move from one developmental stage to the next. The catalytic activities identified as essential to cluster development echo the types of support requested by the researchers at the four aforementioned collaborative research workshops. Many of these catalytic activities lie outside traditional academic research funding frameworks (e.g., multi-stakeholder partnership development), are not eligible costs in traditional funding models (e.g., hiring innovation development staff), and are not widely recognized in reviews of scholarly performance (e.g., community engagement). Without strategic planning and institutional resources supporting these catalytic activities, clusters are likely to maintain current research trajectories and run the risk of not advancing further. Our strategy for supporting the development of clusters of research excellence was therefore centered on supporting these activities.

Implementing cluster support programs

Securing funding for catalytic activities can limit cluster development when external grant opportunities for smaller, more flexible awards are not easily discoverable, require developed applications, and/or introduce significant time delays before cluster-catalyzing activities can occur. Furthermore, because the funding required for these activities does not include direct costs of research, we anticipated that relatively small awards could have large impacts on the clusters' development. Balancing the desire to support the development of interdisciplinary research clusters with the recognition that our university cannot support all emerging research teams, we piloted an internal competition to provide small seed grants to self-organizing clusters: *Grants for Catalyzing Research Clusters*. In this section, we describe our approach to selecting which clusters to support and the rollout of our development support.

Identifying and selecting clusters to support

While institutions may have well-developed protocols for internal competitions, processes for selecting interdisciplinary research clusters have important nuances that require special attention. For instance, traditional research metrics vary across disciplines, and so aggregate metrics are not often meaningful in the assessment of a single cluster or when comparing multiple clusters. Secondly, it may not be possible to quantify the relative contributions of cluster participants when the group includes a wide range of contributions (theoretical, system specialists, network connectors, etc.) and a variety of roles essential for the cluster's functioning (e.g., leaders vs. coordinators vs. participants). Furthermore, cluster activities and goals should vary among teams, obviating direct comparison of goals and activities among clusters.

Despite these challenges, an evaluation process is required to select which clusters to fund and to evaluate funded clusters over the course of their development. Our approach to evaluation of research clusters has been to focus on broadly-defined criteria where clusters can construct their own cases for fit to criteria, using evidence relevant to their cluster.

Example criteria include:

- The cluster addresses one or more complex and key questions facing society and has the potential for transformative impact on the University and on society;
- Proposal leverages cluster funding to attract further funding opportunities;
- Research is interdisciplinary, inter-institutional, and inter-sectoral;
- Demonstrated evidence of excellence in research, scholarship, and/or artistic creation;
- Demonstrated track record of collaboration and/or teamwork (e.g., co-publications, co-supervised students, team grants, etc.);
- Evidence of knowledge translation and mobilization activities (e.g., community engagement, policy impact, commercialization); and
- Ability to achieve a sustained funding model.

Inter-disciplinary panels then review applications and score evidence of fit to the criteria and a strong budget justification that aligns specific activities with goals and expected outcomes. Because applications span multiple disciplines, we ensure that each application receives four independent reviews from researchers in several disciplines and with diverse expertise and perspectives. Reviewer scores are then used to guide an in-person reviewer panel where proposals are discussed among all reviewers and ultimately funding decisions are made.

Although the cluster initiative, program call, and selection processes were designed with consultation from our research community, the resulting funding program was dissimilar to models that are familiar to most researchers. Therefore, ensuring success of the initiative would require training of potential applicants (in preparing applications) and reviewers (in selecting applications). To increase the likelihood of generating a competitive pool of applications aligned with the objectives of the program, we hosted University-wide information sessions where we provided details on the program and responded to questions from researchers. To ensure that the review panel understood (and ultimately selected applications that were aligned with) the intent of the program, the review panels started with a presentation and discussion about the intent of the program before discussing applications.

Catalyzing development of clusters of research excellence

Shortly after announcing the results of our internal competition, institutional research leadership (i.e., Vice-President Research & Innovation, and Associate Vice-President Research & Innovation) met with the leadership team of each cluster individually. During these meetings, we provided high-level feedback from the panel review process in order to refine and focus the clusters' proposed measurable outcomes and the metrics that the clusters would use to monitor their progress towards those outcomes. These strategy meetings serve as an important link between the review process and the cluster activities, and open up direct communication channels between clusters and institutional leadership to help clusters achieve their goals.

Assessing the cluster support program

In the pilot year of the *Grants for Catalyzing Research Clusters* competition, we worked closely with clusters to provide guidance when necessary and to learn from the challenges and successes of individual clusters throughout their award period. After the first round of awards (12 months), we also formally assessed the development of individual clusters and the efficacy of the cluster support program by collecting and aggregating post-award reports. Here, we present our evaluation process, early outcomes of the cluster support initiative, and some reflections on the efficacy of the pilot phase of cluster support program.

Evaluating clusters and early outcomes

Because each cluster defined its own goals and expected outcomes in their application to the competition, we based post-award evaluation of their development on their ability to meet self-identified goals. Clusters were given a post-award outcomes report comparing their proposed outcomes and actual outcomes, justifying deviations. They were also asked to reflect on their experiences and specifically to elaborate on successes enabled by the cluster award and any challenges encountered in developing the research cluster. This information was used internally to evaluate outcomes of the financial investment in the cluster pilot program (i.e., institutional reporting and accountability), to better understand the value of the program from the perspective of the researchers, and to identify opportunities for improvement in the cluster support program (i.e., changes to future competitions). This post-award outcomes report is also attached to future cluster grant applications from the cluster—in addition to their novel proposal being evaluated against the competition criteria, reviewers also rigorously evaluate how well outcomes of previous grants were met.

Less than three years from the launch of our cluster support program, we have already observed impact on clusters and on our institution. At the cluster level, we have observed successful leveraging of GCRC funds with federal, industry, and charitable sources, increased collaborations across organizational units (e.g., Figure 2), the formation of new external partnerships, the creation of novel lines of inquiry, and (to our delight) researchers have reported an increased sense of community belonging and interest in collaborative activities. We view these benefits to the clusters as benefits to our institution, but additional institutional-level benefits include: increased external funding, increased partnerships and community engagement, high return on investment for internal resources, expanded networking opportunities for trainees in clusters, increased communication and outreach, and early evidence of significant impact on research.

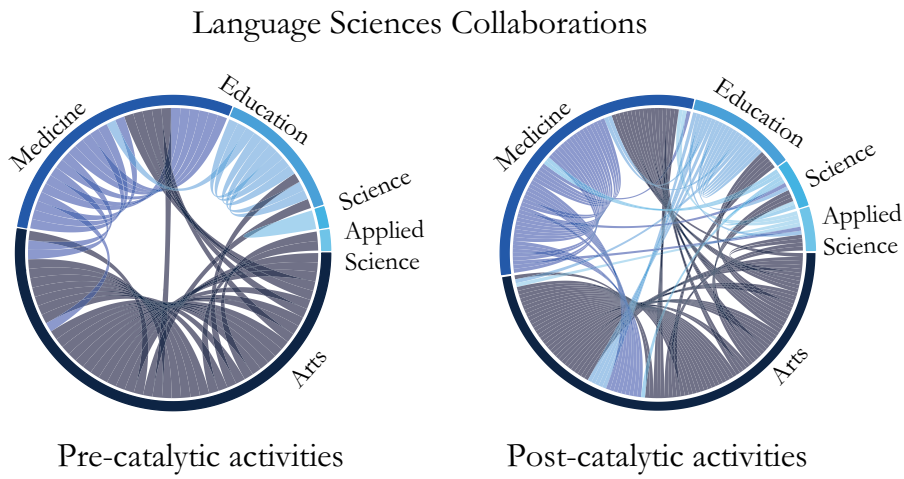

Figure 2. Chord diagram, showing collaborations among faculty members in an interdisciplinary research area (i.e., Language Sciences) across institutional divisions before and after formation of a research cluster. The pre-cluster diagram on the left reveals that most collaborations (as co-authored manuscripts in SciVal) existed within faculties and only a few collaborations existed among faculties. The diagram on the right depicts the pre-existing collaborations plus novels collaborations within and across faculties enabled by the formation of a research cluster (new collaborations are self-reported based on active research projects leading towards publication). The total number of collaborations increased from 47 to 113 and the percentage of collaborations across faculty boundaries increased from 28% to 46%.

Central provisioning of resources vs. providing cash

While the catalytic activities each cluster undergoes ultimately depend on the goals and expected outcomes of the cluster, our initial competition revealed that most clusters share a few fundamental needs, including: communications support, coordination for networking activities, partnership development, funding intelligence, and strategic guidance from institutional leadership. These support needs can typically be best met (in terms of efficiency and quality) through the provision of centrally managed resources. In the second year of our cluster support program, we adopted a mixed support model that provides both institutional in-kind support and cash awards to help each cluster advance. Below, we describe support for developing clusters of research excellence that may be best met through central provisioning.

Coordination. Research clusters universally require coordinated activities among cluster members, and with those activities comes increased administrative burden on the researchers. In emerging clusters, this may be limited to organizing quarterly or biannual collaborative working sessions with the larger group and regular meetings with cluster leaders. In these instances, support can be provided by institutional staff who regularly organize meetings and events or graduate students involved in the cluster (who may have more bandwidth than faculty members for coordination). In established clusters, the coordination activities needed to keep the cluster running productively

may require a full-time staff member dedicated to, or hired by, the cluster.

Communications. Developing and showcasing an internal and external narrative is crucial to the success of emerging clusters. Nearly every proposal we received in the first cluster competition requested funding to design and operate a web presence. Yet, it is unrealistic to expect an employee to work with each cluster separately: institutions will not likely have the resources to fund the development of multiple separate websites from scratch, and it is not generally sustainable to bring in a personal communications consultant for each cluster. Additionally, there is no guarantee that the web design and quality will match the institution's standards. Instead, we provisioned the development of a web template for research clusters from our central IT department and supplied the template to the clusters, saving money and ensuring brand alignment. Our central communications teams then provide communications guidance and support during creation of the clusters' websites and training of cluster members to support on-going maintenance.

Partnership development. In large-scale federal competitions, partnerships across sectors are crucial because they ensure that downstream research users co-create research programs, further leverage funding investment, diversify funding sources, and facilitate knowledge mobilization and commercialization activities. For the same reasons, partnerships are essential to the sustainability of cluster activities. However, even the most highly collaborative researchers may work only in the academic sector. For some researchers that comes as a matter of personal preference, but for many others it may occur because of barriers (actual or perceived) limiting cross-sector exchange. Once clusters have identified their goals and challenges, we are able to connect them with staff experienced in those areas, for instance: partnership development officers (to help with partnership development, innovation plans, and knowledge mobilization pathways [e.g., Phipps, Jensen, Johnny, & Poetz, 2017]); Community Engagement Specialists (in situations where community engagement support is required); Research Funding Development Officers; and Government Relations Officers (when provincial or federal partnerships are key). Established clusters may eventually require their own Strategic Partnerships Officer, but centralized support can get most clusters through the first stages of partnership development (strategic planning and engagement).

Cross-cluster exchanges and workshops. In the first phase of the cluster support program, we met with each of the teams to discuss individual goals and strategies to achieve them. The individualized meetings were helpful in the early phase of the cluster support program, but required significant time investment from institutional leadership. General strategies began to emerge; for the most recently funded clusters, we instead hosted a workshop bringing together all of the clusters to collectively (1) set the vision for the cluster support program (2) share successes and lessons learned among clusters and (3) discuss the effectiveness of and suggest improvements to the cluster support program. The workshop still allowed for institutional leadership to help guide cluster development, but also provided the first venue for clusters to interact and learn from each other's challenges and successes. In a post-workshop evaluation survey, participants unanimously supported the workshop model and have asked that we provide additional programming bringing clusters together to share knowledge in areas of relevance to all clusters (for example: partnership development, governance models, and knowledge mobilization).

Top-down vs. bottom-up approaches

Our institutional approach to supporting research clusters is to identify self-organizing clusters and support grassroots collaborative and interdisciplinary research teams. Through bottom-up processes, natural leaders emerge and, in our early experiences, this is crucial for sustained cluster management and growth. Bottom-up approaches also allow creative linkages to develop that administration could never have imagined, and would never design, (e.g., a violinist and a climate data scientist) and these are the linkages that generate truly novel lines of inquiry. Bottom-up approaches may also have an added benefit of increased participation by trainees and graduate students (though still a preliminary observation, we speculate this may result from organic relationships among researchers). Finally, supporting self-organizing clusters does not require the extensive proactive background efforts by administration that top-down approaches do (see *Scoping baseline collaboration in interdisciplinary research areas* section above), and the onus of demonstrating research excellence and the merits of collaborative synergies can rest with the clusters themselves.

On the other hand, by identifying and promoting areas of priority, an institution can bring additional opportunities and resources to researchers that might not occur without the institutional branding. For instance, facilitating the development of clusters around external priorities or funding opportunities where they are not organically developing otherwise can bring resources to the researchers and institutions that otherwise would not exist. In this scenario, we see the best role of administration as providing strategic support to help mobilize and support the development of clusters in a given research area. Specifically, administration and leadership can assist with connecting researchers across departments/faculties (as described for the interdisciplinary health clusters above), provide examples of frameworks for collaborative research initiatives, help remove barriers to collaboration identified by researchers, and provide incentives to researchers who wish to develop a research cluster in the area of interest (e.g., GCRC competition). Following our efforts to bring together researchers from the four identified interdisciplinary themes, three of the groups submitted an application to the *Grants for Catalyzing Research Clusters* competition—two of these applications were successful and have started developing a cluster through our bottom-up support processes.

Nonetheless, bottom-up approaches to organizing research clusters present their own challenges. Firstly, researchers are rarely incentivized, financially or through award recognition, to pursue cluster activities (Van Rijnsoever & Hessels, 2011). Consequently, researchers may choose to pursue activities that lead to immediate recognition (Landry & Amara, 1998) instead of activities required to organize and manage research clusters, which may be perceived as detracting from publications, grant writing, student training, etc. Secondly, securing the type of funding that researchers need to support cluster growth is frequently a challenge since most important cluster-organizing activities are generally not eligible costs in traditional research granting programs. Finally, the necessity to secure separate funding opportunities for cluster development may significantly delay cluster development (e.g., application processing times and constrained funding windows).

Next steps and future challenges

Disciplinary bias

The guiding intent of our cluster support initiative is to support interdisciplinary collaboration and catalyze collaborative research across all disciplines. However, our initial competition saw an underrepresentation of applications and funded clusters anchored in social sciences, humanities, and performing and creative arts. To create a more inclusive support program, we worked with researchers and unit leaders from those disciplines to refine the competition call, evaluation criteria, and review process. Indeed, these refinements resulted in an increase in clusters led by researchers in social sciences and humanities and, to a lesser extent, the performing and creative arts. However, we still see an underrepresentation of clusters (and proposals) from humanities disciplines. We are continuing to work with faculty and leadership in the humanities and are piloting pre-cluster support to proposal leads from humanities disciplines, but it is important to recognize that a single cluster support program may not ever be able to be fully satisfy the support needs of all interdisciplinary research initiatives. As we continue to encourage scholars from underrepresented disciplines to participate in and lead research clusters, we have also begun to explore additional funding models that may be better tailored to supporting collaborative work in humanities. We recommend that leadership at other institutions regularly engage with researchers in all disciplines to ensure that collaborative research support programs at their institutions are not inadvertently excluding particular disciplinary expertise.

Outcomes reporting

In the early phases of designing and implementing the cluster support program, we were not certain to what extent we would be able to measure tangible impacts of the initiative within and over what timescale, and so our outcomes reporting was dependent upon clusters' self-reporting their ability to achieve proposed goals and expected outcomes. On the other hand, continuing to secure internal funding for the program requires empirical evidence of significant return on investment of the seed funding. We are currently designing a more comprehensive reporting process that will include the assessment of whether major goals were met, but will be supplemented by a structured report on discrete outcomes (e.g., leveraged funding, knowledge translation activities, and new partnerships) and a qualitative impact narrative. This expanded reporting, complemented with analyses of institutional trends (e.g., changes in collaborative publications as seen in Figure 2) will facilitate clear articulation of the value of the institutional investment in supporting collaborative research.

Moving beyond the pilot phase

We now have sufficient evidence demonstrating the success of this pilot program. The next major challenge will be transitioning from a pilot program to an on-going support model at the institution. This will include addressing several unanswered strategic questions, including: How many clusters should the institution be supporting? What is the right balance of support to allocate between newly emerging vs. well-established clusters? Which resources are best provided centrally vs. via funding directly to clusters (e.g., communications support, partnership

development, collaboration facilitation)? At what point are clusters expected to no longer rely on central resources for development? Over the next year, we will focus on addressing these strategic decisions in order to develop a plan for the post-pilot phase of the research cluster support strategy.

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