Research Administrative Burden: A Qualitative Study of Local Variations and Relational Effects

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ABSTRACT

As research administrators look to define their roles as professionals, the need to address perceived administrative burden becomes a valuable next step in improving research administration. A qualitative investigation into the causes of the perceived burden identifies local variability of research administration as regulatory burden for those research administrators looking to be seen as professionals by the researchers performing human subject research.

INTRODUCTION

Research administration history in the twentieth century included high-profile public cases of scientists conducting unethical investigations, as well as unacceptable treatment of research subjects. Physicians were historically held solely and personally accountable to their code of ethics knows as the Hippocratic Oath, which simply states, "do no harm" (Shuster, 1997). However, as examples were made public, like the Tuskegee Experiment, public trust was eroded (Kelch, 2002) and led to public outcry. These outcries are most famously linked to public events such as the Nuremberg Trials. Results included

questioning of the unfettered autonomy granted to scientists.

In conjunction with the public outcry, the research enterprise grew across U.S. academia, with little or no investigation into how this increase in requirements affected the practitioners of modern studies (Sugarman, 2005; Wagner, 2003). This hole in the literature has caused great tension at the local level as research administrators look to define their work as a profession.

LITERATURE REVIEW

Most research in America completed in academic institutions is led or overseen by groups of faculty scientists commonly known as Principal Investigators (PIs). The definition of what constitutes the expectations or requirements of a PI may be different at each institution, often causing confusion. However, the PI is the responsible party and is defined by the National Institutes of Health as: "The individual(s) designated by the applicant organization to have the appropriate level of authority and responsibility to direct the project or program to be supported by the award" (NIH, 2013).

PIs work in close collaboration with teams of administrative staff called research administrators (RAs), often serving in staff roles in the various groups that make up the research administration department. Research administrators historically come from two professional backgrounds, either as scientists themselves (Mainzer, 1963), or from among those who have administered non-research activities (Bush, 1956). A current study of the definition of research administrators is ongoing, and includes a look at expected roles and activities (Collinson, 2006, 2007).

Research administration is a process that has tasks that take place during the entire lifecycle of a research project. Research administrators work closely with PIs before, during, and after research has begun and are tasked with ensuring the verification of compliance. For example, before work starts, many studies must be reviewed to receive approval. Once work has begun, the tasks related to research administration may include periodic verification of progress that may include financial or regulatory requirements. This verification and compliance time can take a considerable amount of effort, and the communication or attitudes among these groups may cause concern (Pelz, 1959). This concern has been present since the earliest days of research administration. In Kaplan's 1959 article, "The role of the research administrator", he stated: "The research administrator is seen as a 'man in the middle,' caught between the frequently conflicting goals of the research scientist and the research organization. In his

attempts to maintain controls (many of which may be required by 'higher authority') over the allocation and use of the scarce resources of the organization, the administrator is the focal point for the scientist's grumbling about 'red tape' and worse, unnecessary interference with research" (Kaplan, 1959 p. 20).

In addition to expectations and regulations, the literature describes the splintered nature of complaints and solutions offered with regard to Research Administrative Burden (RAB). However, in some cases, the literature may include articles on other issues. Often, articles may not be directed at the topic of research or research administration, but the broader issue of considering the requirements to have the study approved by Institutional Review Boards (IRBs) (Arnold, 2012; Kramer, 2012; Zaren, 2013).

In human subjects research, the IRB board makeup has two major types of associates: the office staff, known as research administrators, and the board members (Kennedy, 2005), one of whom serves as the IRB chair. The IRB chairperson plays a key role (Kaur, 2015) and sets the professional atmosphere for the board. The diversity of the members – race, gender, and culture – is essential (Code of Federal Regulations, §46.107). In a 1998 study, Bell found that IRB board personnel are "predominantly white and well-educated, with chairs and members more likely to be male, and administrators more likely to be female" (Bell, 1998 p. viii).

Title 45 of the Code of Federal Regulations §46.108 describes IRB functions and operations. §46.103(b)(4)(5) dictates that the IRB legally be required to have documented procedures for the review of both initial and continuing research. This regulatory requirement provides the IRB the authority to specify studies that need more than an annual assessment. Additionally, the regulation provides the Institutional Review Board with the ability to enforce the rule before any additions or changes to the research, known as modifications, are exercised.

Regulatory Codes §46.109 through §46.114 dictate the process for reviewing research. These requirements create an underpinning infrastructure for analysis while allowing for additions at the local level to meet institutional expectations. The regulations make it clear that the Institutional Review Board has the authority to review any research activities defined as exempt, expedited or full board and approve or reject the proposals. However, no matter the outcome, the IRB is obligated to inform the principal investigator of the decision formally. Communication, or lack thereof, between

the IRB and the investigators is important and is often considered a pain-point contributing to Research Administrative Burden (Adams, 2014; Greene, 2006; Kramer, 2012). Additionally, the Common Rule stipulates that the IRB may waive documentation of informed consent. As a baseline, the IRB shall conduct a continuing review of the process at least annually except where determined in §46.108. If an IRB warrants a suspension or termination of a previously-approved study, IRB options include a written statement citing the board's decision.

Beyond the formal regulations that dictate the operation of human subjects research, much has been written regarding the organizational theory of institutions and investigators that conduct research. Articles that describe Research Administrative Burden call on regulatory history to discuss the legality of IRBs. RAB also includes anecdotal evidence, scope creep, risk tolerance, the different types of human research including differences between medical and social sciences, the demands of limited funding, and the needs of multisite (collaborative) studies. Differences in local implementation of the regulations, as well as the actual function of IRB offices, are often only measured by the number of days that it takes to approve a study.

The history of scientists conducting research has had a significant influence on the organizational makeup of modern-day research institutions where scientists are encouraged to make their decisions as they set their research objectives (Harrison, 1974) and be an objective observer of the complex world (Hatch, 1996). The call to organize science started early in the first half of the twentieth century. After World War II, the concept of federally funding research was still a new idea but was gaining traction.

In 1945, Bush wrote "Science: The endless frontier." In the article, he explained how science should be a concern of the government – a novel idea at the time. The Bush document can be considered the intellectual parent of federally funded research, including both policies and expectations of today. Bush directly called for the federal government to sponsor research. His opening of the article set the tone: "Scientific progress is essential" (Bush, 1945 p. 231). In the middle of the twentieth century, the federal government was determined to support the opening of new frontiers. Although maps were complete and ships discovering new shores were less common, Bush argued that the next frontier for government assistance should be science. He called on the federal government to create favorable policies, provide stable funding, and set forth

processes to allow for freedom of inquiry with involved academia as partners in this expanded research platform. He maintained that the scientific community should be seen as part of the public welfare. Bush contended that basic science leads to new understanding and that new knowledge gained can be used to improve the lives and safety of citizens (Bush, 1945).

However, in 1945 there was no formal policy for federally funded science, and therefore no path to take the basic science of the laboratory to the public. To do this, he suggested the federal government use public funds to foster the research of academic institutions. Bush also called for a plan and roadmap to ensure that scientific talent is encouraged for future generations. Throughout all of his declarations, Bush called for ongoing government support with the creation of a National Research Foundation. This article provided the foundation for modern-day research—its recommendations are fundamental to the scientific community's quest for knowledge. By the twenty-first century, the National Science Foundation was spending close to 3% of the total Gross Domestic Product (GDP) on related research activities totaling almost $150 billion (Saha, 2011).

When the Common Rule transferred the responsibility for research administration away from the investigators to an Institutional Review Board, the concept of Research Administrative Burden quickly became the focus of concern in the published literature. In the 2009 article, "The FDP Faculty Burden Survey," the authors noted that Research Administrative Burden accounts for up to 42% of investigator time. The IRB process is one of the largest burdens listed (Rockwell, 2009). In his 2008 article, Reeser noted, "Despite the Federal mandate to oversee research involving human subjects, "IRBs are often lightning rods for poorly veiled criticism and complaints, seemingly from all sectors of the research enterprise" (Reeser, 2008 p. 30). The breakdown of topics in Research Administrative Burden include anecdotal evidence, the legality of the regulations themselves, variation in analysis, both on-site and informed consent processes, risk tolerance, and IRB turnaround times.

The concept of Research Administrative Burden is difficult to define and may vary from location to location based on the type of research and local implementation and differences in interpretation of the regulations (Kaktins, 2009). Therefore, when reviewing the literature, it's clear that authors have documented and acknowledged s that the findings may be incomplete or anecdotal. In a 2014 article, Adams mentioned that the evaluation of something is "unavoidably relative" and

therefore it may be difficult for the community to reach agreement on the terms and definitions (Adams, 2014). Jones noted that "anecdotal evidence suggest that many investigators may not be familiar with the IRB system or what criteria are used to evaluate a research proposal" and therefore providing a single answer may be beyond the current scope (Jones, 1996 p. 806). Resnik, in a 2015 article, "Unequal treatment of human research subjects," explained the dichotomy of the current explanation and the expectations researchers hold for themselves. He noted that scientists acknowledge and understand that anecdotal evidence is not sufficient (Resnik, 2015). Consequently, additional information is needed to find meaningful answers (Menikoff, 2007). Although a complete picture may not be possible, exploring the legality of the approved laws serves as a first step in the discussion.

The legitimacy of IRB and other research administrative functions is a constant topic of debate in law reviews and peer-reviewed journals; the question of legality remains. In her 1980 article, "Government regulation of research," Seiler stated that, "Although neither a constitutional right nor an exact definition exists, the value of academic freedom must be balanced against the value of regulation" (Seiler, 1980 p. 26).

The year 2004 saw the publication of one of the most referenced peer-reviewed articles regarding IRB legality. "The new censorship: Institutional review boards," was written by Hamburger and published in the *Supreme Court Review*. In this article, he argued that by restricting scientists' rights to conduct research as they wish, IRBs, and therefore the regulations themselves, are infringing on the First Constitutional Amendment and constituting a new type of censorship (Hamburger, 2004). The First Amendment reads:

> Congress shall make no law respecting an establishment of religion, or prohibiting the free exercise thereof; or abridging the freedom of speech, or of the press, or the right of the people peaceably to assemble and to petition the Government for a redress of grievances (U.S. Const. amend. I).

In his article, Hamburger maintained that much research on human subjects causes little or no harm and that the licensing of both research and researchers infringes the first amendment restriction on free speech (Hamburger, 2004). Hamburger referenced the Beecher article from 1966 and suggested that public anxiety has led to the licensing and censorship of research. Although the right to conduct research on human subjects has never been tested in the

Supreme Court, the case of *Sweezy v New Hampshire* protected a person's right to present a lecture at a university (Heimer, 2010).

The First Amendment is not the only legal challenge that has been presented to question the human subjects regulations. Additional articles contend that IRB offices do not provide due process of law for investigators and evoke the 14th Amendment as argued by Stoddard in 2009. The 14th Amendment Section 1 calls for the due process of law.

> **Section 1.** All persons born or naturalized in the United States, and subject to the jurisdiction thereof, are citizens of the United States and the State wherein they reside. No State shall make or enforce any law which shall abridge the privileges or immunities of citizens of the United States; nor shall any State deprive any person of life, liberty, or property, without due process of law; nor deny to any person within its jurisdiction the equal protection of the laws. U.S. Const. amend. XIV § 3.

Stoddard argued that by failing to provide necessary due process, IRB regulations and the decisions of IRB boards are, in fact, unconstitutional. The argument made is that scientists have no formal right to appear before the IRB committee in response or dispute of a decision. Furthermore, and according to the Common Rule, once a decision is made a third party cannot overturn it. By not allowing the proper due process, IRB committees are illegally disallowing investigators their constitutional rights. (Stoddard, 2009). Both articles agree that science will suffer until improvements are incorporated.

Conversely, others have argued that the regulations are indeed constitutional. Beldsoe stated that federal IRB rules and practices do not constitute censorship. Instead, he argued that the institution, acting in the federal government's interest, is obligated to meet expectations outlined in the Common Rule. If there is any misunderstanding of these rules, the discretion allowed the local IRB may be the exact reason for the concern (Bledsoe, 2007). While Menikoff agreed that regulations are most likely constitutional, the local processes or operations may be suspect, and the solution would be to review and better understand the local implementations (Menikoff, 2007).

Because IRBs and institutions have flexibility in their regulatory scope above the baseline outlined in the Common Rule, this variability causes confusion from a researcher perspective and therefore serves as a regulatory burden for scientists looking to conduct research. As Stark noted, "The important question is not whether

regulatory decisions involve local discretion but rather how this discretion is enacted" (Stark, 2007 p. 782). Whitney suggested that when investigators perceive extreme challenges with IRB approval, the problem may be rooted in the flawed local implementation of national directives. As noted in the Common Rule, institutions have the power afforded them to decide how the rules and expectations are implemented. These local decisions are described as "unpredictable" (Carline, 2007), confusing, costly (Kaktinks, 2009) and even irrational (Whitney, 2008). This discretion has caused much concern in the arena of a perceived research administrative burden as scientists feel that local implementation is neither efficient nor fair (Burris, 2006).

These criticisms can stem from some variations in the processes. Various submission procedures, including paper versus electronic (Dyrbye, 2007), may prevent a researcher from using a single form or process, even locally, as some institutions have moved to specialized IRBs for different types of research activities (Levine, 2008; Lindenauer, 2002; White, 2007). Scores of submissions can cause delays (Gold, 2005) due to locally created and enforced forms that interpret the Common Rule differently based on local preferences. These variations produce large differences for the supposed same process across U.S. research (White, 2007).

Beyond local variability, this discretion in institutional research administration implementation is more clearly seen in studies that cross institutional boundaries. These multisite studies work with several research administration offices to obtain approval. Depending on the type of research, several committees or IRB reviews may be navigated, required, and approved before research may proceed. The rate of academic collaborations continues to increase as researchers who have created a tightly knit social/career network, look to work with each other even across institutional boundaries (Clark, 2010). Additionally, clinical research has moved from studies funded by single investigators to larger multisite studies financed by external sponsors (Emanuel, 2004) who may expect collaboration as a funding requirement (Lee, 2005). In practice, researchers or teams of researchers who wish to utilize multiple institutions for recruitment sites complain that they are required to contend with drastically different expectations. This concern for multisite studies is one of the most prolific topics in published articles on research administration. The primary complaints relate to delays, increased cost, variances, inconsistencies and lack of communication

(Abbot, 2011; Ahmed, 1996; Bluestein, 2007; Petersen, 2012). These stated problems are the greatest source of tension between investigators and administrators (Burke, 2005).

Two arguments raise concern and demonstrate the frustration voiced for multisite studies. First, local review by different IRB committees is continuously present since the application of federal regulations occurs within the local context. However, the flexibility designed into the Common Rule may leave too much ambiguity to the local process, threatening the validity of local review (Dyrbye, 2007). Second, the expectation for a local review is solely a bureaucratic need that is unnecessary with the allowed use of central IRB review (Zywicki, 2007). Reports of local issues and concerns led researchers to call for central IRB review (IDSA, 2009; Perlman, 2012; Pogorzelska, 2010; Stair, 2001; Stewart, 2008). Central IRBs are review boards not associated with a single investigator or institution, but instead are outside of the boundaries and can serve multiple research sites. Some central IRBs, such as the National Cancer Center IRB, known as the CIRB (CIRB, 2016), currently function and are reported to have reduced duplication of work that would be required by local review boards. The literature calls for the reduction of effort by central IRBs where appropriate in order to reduce study personnel by up to one full-time employee (FTE) and reduce the overall study time by up to one year (Vick, 2005).

The process of informed consent is another concern of researchers who feel that local variability has caused Research Administrative Burden. Tied closely are multisite reviews. The process of informed consent is necessary at each recruitment site to be approved subsequently by each local IRB. As noted in the Common Rule, local IRBs have the ability to require changes to waive or modify informed consent. That authority has caused problems. A current literature analysis showed that informed consent is one of the most requested changes needed for local assessment (Abbott, 2011; Kent, 1999; Stair, 2001; Zywicki, 2007) and that the changes often are opposed to the task of protecting subjects. Bell argued that 60% of IRB chairpersons interviewed noted that informed consent documents often contain a complexity that is vague or unnecessarily technical (Bell, 1998). Adams reported that in a survey of 203 researchers, the opinion and feeling were that instead of serving to protect participants, these documents are being used as legal documents to protect the institution (Adams, 2014). This documentation is one of the key points when discussing the fact that risk tolerance

is now a major concern for agencies and the researchers who are obligated to meet regulatory expectations (Cartwright, 2013). However, Rivera stated that although the process may be complicated, the law is essential: "In moments of frustration, it is important to keep in mind that good treatment of research subjects yields good science. Finally, the protection of human research subjects' rights and welfare is not only the right thing to do-- it is the law" (Rivera, 2008 p. 984).

Another major concern raised by researchers is the low level of risk tolerance seen primarily in institutions and secondarily by the investigators themselves. When new regulations pass, organizations may act defensively by implementing new local requirements. Some have argued that these institutional concerns lower risk tolerance. With new lower levels of understanding comes the opportunity for the expansion of research administration. This expansion, often tied to new requirements, is thought to cause more Research Administrative Burden as studies that were previously considered low-risk are now highly regulated (Hamilton, 2011). The new prerequisites, as implemented, are often part-and-parcel of the office of research administration and required for IRB review and approval. This expansion, called Mission Creep (Howard, 2010) or Ethics Creep (Guta, 2013;Haggerty, 2004), is closely associated with institutions opting to require more than the baseline regulations and with researchers being unaware of what the requirements are for their studies amid growing bodies of direct and tangential rules.

Considering perceived lowered risk tolerance, one of the most pressing issues raised regarding perceived Research Administrative Burden is the fact that diverse types of research are different (Hyman, 2007), with particular attention given to all research that is not medical in nature. As per the Common Rule, there are expectations for research as defined in the law– yet beyond some exemptions stipulated, there are no expectations for different types of studies in the formal regulations.

However, the breakdown between medical versus social science research is well documented in peer-reviewed journals. Arguments that social science is foreign to IRBs or the institutions is a valid point at times. In the 2007 article, Ashcraft stated that most of the IRB literature focuses on biomedical research at the cost of exploring social and behavioral research (Ashcraft, 2007). This lack of institutional or regulatory understanding results in social science research falling under the most stringent requirements for biomedical research.

Although the risks of social experiments have not increased, the scrutiny of the projects has grown "exponentially" (Lincoln, 2004). This heightened scrutiny is at best felt to be "silly" (Burris, 2006) and at worst a threat to the proposed research (Dingwall, 2007), including qualitative studies (Pollock, 2012).

These arguments, while prevalent, are countered by other voices in the published research. In a 1980 article by Seiler, regulators felt they were compelled to include social research in the regulatory scope just as they included all types of academic studies in the regulations (Seiler, 1980). Stark, in her 2007 article, reviewed the historical nature of medical versus social science rules. She noted that the 1966 announcement by Surgeon General William Steward was clear: the social sciences required oversight just as the medical researchers did (Stark, 2007). However, while this debate continues, the idea of student research provides another complex agreement regarding the nature of review for yet a third type of research.

Student research is thought to be a major hurdle for researchers wanting to mentor students looking to progress as scientists. As students go to school and learn to be research scientists, an instructor is expected to oversee their initial research and guide them through required processes. Students hear stories about the "horror of the IRB" (Burke, 2005). They also hear that IRBs are known as "Committees for the Prevention of Research of Human Subjects," (Stark, 2007). Comments like these could lead to non-compliance.

The main cost of these burdens, as discussed in the current literature, is research misconduct from those scientists who would rather ask for forgiveness than ask for permission, or who violate ethics when they feel they are being treated "unfairly" (Martinson, 2006). This most frequently occurs with researchers who do not ask for IRB permission to initiate a study (Bell, 1998). Another situation as described in the De Vries article, "What do IRBs look like? What kind of support do they receive?" evokes concerns raised in the article by Beecher. Researchers trying to determine the best course of action for providing a drug of choice may choose to ignore research processes as they see the informed consent for this type of study as a "ridiculous request" (De Vries, 2006). Giles described this non-compliance, writing that collecting research before IRB approval is a response to lengthy approval times (Giles, 2005).

METHODOLOGY

A qualitative method was chosen to investigate the issue of local variability and research administrator issues. The qualitative research conducted here follows the model by Glaser and Strauss from their 1967 definitions and expectations of Grounded Theory methodology. This experiment was approved by the University of Texas at Dallas Institutional Review Board and used the older and more formal Grounded Theory process. All subjects were provided consent forms in which they were asked to agree to answer the questions as approved.

The creation and process that defines a Grounded Theory study have changed in the last few decades. What has not changed is the core makeup of the model specifically exploring the action or movement in an activity while trying to explain the program or process under research. In chapter 4 of the 2013 edition Grounded theory: Qualitative inquiry and research design by Creswell, the author defined grounded theory and noted that first-and-foremost the study must focus on a process (Creswell, 2013) such as the IRB submission. The goal of studying the IRB process is to develop substantive and general theories surrounding the concept of Research Administrative Burden. The structure of data analysis in Grounded Theory is rigid or free-flowing, depending on the chosen model. The more recent versions are less structured, but the originators of the model felt that structure allowed for more generalization that permits a single experiment to explain a conceptual model (Creswell, 2013). In turn, the theoretical model should enable the explanation of similar processes for a value-added effect. As noted, the Grounded Theory method has changed over the decades; however, no matter the model chosen, the result is to develop a theory for why the process or action behaves as it does through data accumulation (Heath, 2004). Data-gathering includes detailed interviews and supports memos drafted during the collection process. This robust collection of materials allows for deeper understanding once the interviews have concluded.

Grounded Theory suggests that to achieve saturation or an understanding of the process, the researcher should conduct 20-30 interviews (Creswell, 2013) for a total study population. In this study, respondents had been in research administration for more than three years. Age was captured as a range to determine whether interviewees had served in other roles during their professional career or if they had dedicated a large period of their working life to the field. Their highest academic degree was noted to determine

the level of education. Additionally, a marker question was posed to ensure the subject had an understanding of the most common professional language used in research administration. These demographic variables, paired with the tag question, helped determine whether participants were knowledgeable in the field of research administration and research in general.

The study sample was chosen from a pool of subject matter experts and categorized into three groups. The first group were research administrators.

Research administrators were selected to gain a greater understanding of the U.S. research administration process and any potential burden. The National Council of University Research Administrators (NCURA), which was founded in 1959, served to identify the possible recruitment sample. The NCURA website states that: "NCURA serves its members and advances the field of research administration through education and professional development programs, the sharing of knowledge and experience … by fostering a professional, collegial, and respected community" (NCURA, 2016a, n.p.). Members join NCURA and other professional organizations for several reasons, including professional development (Roberts, 2005). NCURA consists of eight regions that serve the United States and foreign nations that may request funding from U.S. sources. Every year, each region hosts a local conference; the central administration hosts a national conference for members. The organization has grown over time and had an estimated 1,500 total members as of 1990 (Nixon, 1990). This total has grown to over 7,700 members. Region Five (V) contains both Texas and Oklahoma as members and boasts a diverse membership of over 650 faculties and staff from research institutions and private industry (NCURA, 2016b). The Region V Executive Committee agreed to provide access to active members for this project. Subjects were recruited through Region V social media, such as Facebook and the *NCURA Magazine*. The NCURA group provided access to the remaining two groups.

The second group of participants was self-selected researchers. Based on the interview questions, participants identified themselves as scientists who had participated in research and research administrative activities, including paperwork submission for studies conducted in the United States. As expected, this group held a majority of terminal degrees such as Ph.D., MD or JD. The second group sample came from multiple institutions, so as not to bias the

experiment from a single research administration or IRB process.

The third sample group was a hybrid of researchers and administrators. These participants were creators of research and research materials who had a role as a committee member, chair, or staff member within a research administration office, such as the Institutional Review Board, Institutional Animal Care and Use Committee or Conflict of Interest Committee. The sample was recruited from multiple institutions and locations to assure variation in processes. Their experience on both sides of the administrative process provided unique insights. See Figure 1 for a visual breakdown of the total population and subgroups.

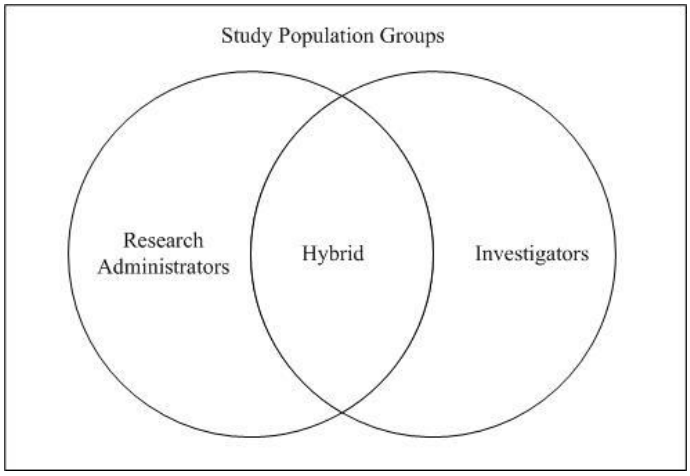

Figure 1. Study Sample Groups

The survey questionnaire contained fewer than 20 questions. The questions were framed to capture demographics, longevity in the field, and responses to open-ended questions. See the Appendix for the full list of questions as approved by the IRB. The investigation was formulated from the survey and served as proxies to larger issues of research administration. The responses formed the basis of the research questions and hypotheses posed in the research. In addition to the demographic data gathered, the remaining inquiries were open-ended, unstructured questions and prompts designed to support the Grounded Theory model. Subjects were asked neutral issues such as: "Tell me about your experiences with Research Administration," and "How do you explain your job to people outside of Research or Research Administration?" Subjects then were asked to provide their impressions of the best and least desirable parts of research administration. Researchers' feelings about regulatory burden were expressed through the question, "Do you feel that over your

career are more regulations, less or about the same amount of regulations?" Additional areas of interest related to collaboration, the nature of the rules required for research, and researchers' feelings about the history of the growth of research administration. This blend of items allowed the Glaser and Strauss methodology of Grounded Theory to be applied.

Interviews for this experiment were conducted primarily over the telephone or by email. The materials were submitted to the researcher via text in email or audio-captured during the interview. When available, in-person one-on-one interviews provided additional insight into the topic. Each meeting lasted less than one hour. As noted in the approved IRB protocol, each audio interview was recorded and transcribed. As expected in the Grounded Theory methodology, memos were captured during the interview process to allow for later coding.

Grounded Theory, as modeled by Glaser and Strauss, has a fixed method of collecting and reviewing data to describe the experience and to create new theories that describe the process or activity under consideration (Creswell, 2013). This process is referred to as coding or the arrangement of data into useful categories by the researcher. Although the initial concept was designed and implemented in the late 1960s, new tools are available that can be used to support the process.

The process for managing and coding the data was based on methodology used in dissertation research by Spencer. It combined traditional interview transcription, the creation of memos and a qualitative data software suite called NVivo. NVivo is an unstructured database program selected to teach qualitative methods at the University of Texas at Dallas in the School of Economic, Political and Policy Sciences (EPPS). Both paper and electronic methods rely on the creation of meta-data, or secondary sources that describe the primary content. While a valid Grounded Theory study may rely on paper-based data capture, there are distinct benefits to using NVivo.

The interview transcripts consisted of Microsoft© Word™ documents transcribed directly from the audio (MP3) files and then loaded into NVivo. Once in the NVivo software, the system allows for easy use of the captured demographic information and initial review of the materials collected in the field. Memos considered secondary sources of data were associated documents that were tied to the interviews in the software suite.

Once the primary interview data and secondary metadata were entered into the

software, data analysis via open coding began. Open coding is the process of identifying labels for the conceptualization of data retrieved upon initial review. It is the first pass of coding within the Grounded Theory methodology—the researcher moves through the collected material and memos by reviewing and identifying groups of useful content within the data. The Glaser and Strauss model calls for a strict rigid first pass. To accomplish this task, the questions, as numbered, were coded using a standard naming convention. The standard naming convention allowed for easy sorting within the software and reviewing the answers across all interviews on a single display window on the desktop.

One of the main benefits of a software suite such as NVivo is the ability to enjoy the simplicity and structure of computer databases while allowing the manual aspect of Grounded Theory Coding to be accomplished. The Glaser and Strauss Grounded Theory requires the researcher to comprehend the meaning conveyed through the transcript. Being able to jump quickly and confidently between interviews and themes in the software allows for the necessary constant comparison process of distilling responses into usable data needed to progress in the methodology. The NVivo software tool allows researchers to compare data quickly using a number method that aids in visualizing data (Leech, 2011).

The system allows for the striping and highlighting of data sources to enable visual representation of coding. Striping is the process in which NVivo identifies sections of the text that have been coded and those that have not. The grouping lists the stripes. Highlighting allows the coded to be easily reviewed in the body of the article to ensure contextual consistency. Examining the interviews with striping visualization turned on allows one method of constant comparison. The user of the software can quickly determine if any relevant sections were either not coded or coded incorrectly and move to the next step of Axial coding.

Axial coding, or theme motif building, is the process of data distillation in which codes are tied together to form overall themes and reduce the number of codes from the open first pass. Axial coding is done through inductive (i.e., letting the themes emerge from the data) and deductive reasoning, starting with a theory held by the researcher. This process is completed by reviewing existing codes and reassigning them to new groupings. The goal is to locate the primary characteristics or axis of the process and define a small subset of relationships or experiences through a process that can be described as the initial findings of the research process

that can support the further distillation of experiential data.

Selective coding is the reduction of the previous pass of coding themes to form a singular or small group of primary relationships in the data. This final step in code reduction is the core category for the particular experience and serves as one of the last steps of theory generation that describe the process. Through this process, helpful answers derived from the data serve as an endpoint for Grounded Theory.

RESULTS

The literature review showed that the requirements of research administration varies widely based on the nature of the human subjects research protocols and needs within the local institution. These complexities are at best poorly understood. Often the finer points are argued in the public journals, leaving no clear path for policymakers or tools for practitioners to measure their environments. The methodology led to information on and enabled discussion about the process that should be utilized in the interviews.

As dictated by the Grounded Theory methodology, the process requires between 20 and 30 responses to reach saturation. According to Creswell (2014), no additional information may be retrieved by conducting more interviews. The study sample consisted of 27 responses. The work goal minimum for each interviewee (three years working in research) was exceeded, and the average for the cohort was 20.5 years with a range between 5 and 51 years. The participant age range was captured in the interviews—the group tended to be older, with only two responses within the 25- to 35-year age range. There were nine responses in the 35- to 45-year age range, nine responses in the 45- to 55-year age range, and seven respondents reported being over 55 years old.

The survey itself consisted of 17 to 19 questions. The document originally had 19 questions, but a study modification was submitted to the UT Dallas IRB office, during the process, to reduce and rephrase some questions to better represent the three types of subjects interviewed. This change was helpful for the remaining participants who were able to understand the requests more clearly.

The breakdown of the sample collection into three groups with experience in research and research administration provided a deeper understanding of the current process from individuals familiar with multiple angles of the same issue. Subjects were asked to self-select their role in research or research administration and place themselves into one of three categories defined by a research

administrator, scientist or researcher, or a hybrid of both (such as a board member).

The first group, research administrators, consisted of members of NCURA Region 5. To avoid maturation, members who were previously in Region 5 but had moved to other regions due to job advancements were included. A total of 10 self-selected NCURA members represented 37% of the total interviewees.

The second group consisted of self-identified researchers. Of the total 27 subjects, six stated that they were solely researchers and did not have any back-office research administration experience. These people were recruited for this study, responded from multiple institutions across the U.S., and reported varied scientific backgrounds. The second group was formed to reach a wider audience of those people who submit paperwork to several research administration offices.

The third group consisted of members who did not fit into either of the two groups and self-identified as having both roles and tasks of both research administrators and researchers. This group included scientists who sit on research review boards, such as Institutional Review Boards or other research-related committees, and therefore have knowledge of and insight into both sides of research administration. The individuals who self-identified in the hybrid category represented 11 members of the total study population and was the largest survey group.

These three groups represented the complete data set. Survey responses were prepared (transcribing, coding and reviewing the data) and loaded into the NVivo qualitative research software suite for analysis.

The audio interviews were transcribed from the sound files. Over the course of the 27 meetings, the primary recording device failed twice, and the researcher had to rely on backup audio devices and the memos collected during the interview process. The memos were converted and loaded into NVivo as PDF files to allow for comparison between the notes and audio transcriptions. With interviews and memos loaded into the NVivo software, coding of the interview data began.

The first round of coding, described as open coding, called for the creation of groups or nodes of data to categorize the responses. The term *Node* describes a grouping mechanism within the NVivo software suite that behaves like folders in a Windows environment. The Glaser and Strauss model calls for these groups to be more structured. The first pass of coding was labeled Q1, Q2, and Q3 so that the responses were clearly identified with the corresponding question. The questionnaire

consisted of 17 questions. The grouping of the questions into sections allowed demographic data to house similar information. The 27 interviews, each represented by a node in Nvivo, matched the information provided from the interviewees to the questions. See Figure 2 for the NVivo Generated Content Word Cloud that describes the content of the interviews.

Figure 2. Interview Content Word Cloud

The word cloud is a generated visual representation of the collected data. This tool allows the researcher to review specific words that have a high frequency within the content of the interviews and assist the researcher in ensuring that relevant topics during coding are not missed. With the first pass of information loaded into the software, the second round of coding began.

The next step was to Axial code the data. Each primary node was opened and reviewed. Based on this round of review, new nodes developed. As themes emerged, a new series of spawned nodes evolved under the heading of Axial coding. NVivo allows for groups of nodes to be clustered for easy sorting and review. These new nodes were not tied to any specific question but instead were associated with the content found in the answers provided. A total of six themes emerged from the interviews. See Table 1.

Table 1
Axial Coding Results

Theme	Number of References
Risk Aversion	3
Enforcement of Regulations has Increased	4
Desire to be Seen as a Professional	12
Local Requirements	14
Teamwork	20
Complex and Changing Regulations	30

The six themes that arose from Axial coding were: (1) Risk Aversion, (2) Enforcement of the Regulations has Increased, (3) Desire to be Seen as a Professional, (4) Local Requirements, (5) Teamwork, and (6) Complex and Changing Regulations. These themes were found to be important across several interviews. The frequency occurrence of each overall theme demonstrated the relative importance of the topic to the interviewees. Each theme had context and a place in the overall activity of research administration.

Subjects voiced the theme of *Risk Aversion,* which closely correlated to the choices made by local institutions to enact regulations perceived by these subjects as unnecessary or onerous to the researchers or to the IRB office itself. The consensus was that local regulations often are implemented to prevent audit risk. In one example, the institutional decision to require a new control was made outside of the scope of research administration but which affected both the IRB office and the investigators who submitted paperwork.

The next theme of *Enforcement of the Regulations has Increased* emerged in response to the question regarding some total regulations. It was the opinion of some interviewees that the absolute requirement for regulations may not have significantly increased during their tenure in research but that enforcement of the existing regulations had increased. The example that was repeatedly given related to the fiscal conflict experienced by interested parties. The Bayh-Dole Act which was enacted in 1980 and which provides for the regulatory enforcement of financial conflicts of interest was not heavily enforced until the early twenty-first century.

The theme, *Desire to be Seen as a Professional*, was created to address the fact that research administrators are seeking to

be recognized as more than simply administrative staff. This theme arose several times in interviews with both the research administration group and the hybrid group. As the complexity of research administration increases, practitioners desire to be recognized as professionals who have chosen a specific educational or career path.

The theme of *Teamwork* was raised multiple times by all groups interviewed. Working together to support research was a topic in which all groups showed keen interest. The initial discussion came from research administrators who wish to be seen as supportive of the researchers, as well as part of the team that ensures that research is moved forward without delays due to excessive regulations.

The concern over *Local Requirements* was a theme that sometimes emerged during the interviews. Individuals in both the Investigator and Hybrid groups saw these local implementations and the discretion for interpreting federal regulations as being issues of concern. Interviewees noted that as the processes changed at each institution where they worked, it became harder to keep up and maintain compliance.

The theme of *Complex and Changing Regulations* was the finding with the greatest number of references in the entire set of interviews. All groups noted that the landscape of regulations is constantly changing and the complexity of the rules causes confusion and the possibility of non-compliance.

The process of Axial coding, as dictated by the model, offered great insight into the thoughts and feelings currently in the minds of researchers and research administrators. As revealed, themes indicated through the content of the interviews that they needed to be grouped and distilled to take the next required step in Grounded Theory.

Selective coding generated the final relationships among the above themes that served as the end-point of the Grounded Theory model. These relationships created the foundation for theory generation into an understanding of IRB submissions.

The themes, as discovered, led to the identification of three relationships through the process of selective coding. The themes were: (1) the changing variability of local requirements, (2) teamwork is needed, and (3) research administrators wish to be seen as professionals. Both (2) and (3) served the needs of this study. They were developed to enable an understanding of the components and definitions of Research Administrative Burden. The third theme, while interesting and expected from the questions posed, will be saved for future research.

Local requirements were distilled from four of the six identified themes: (1) Risk Aversion, (2) Enforcement of Regulations Increased, (3) Local Requirements, and (4) Complex and Changing Regulations demonstrate the variability. These four central themes as shown in Figure 3 have a single relationship that runs like a thread through the interviews and points to an opportunity for improvement.

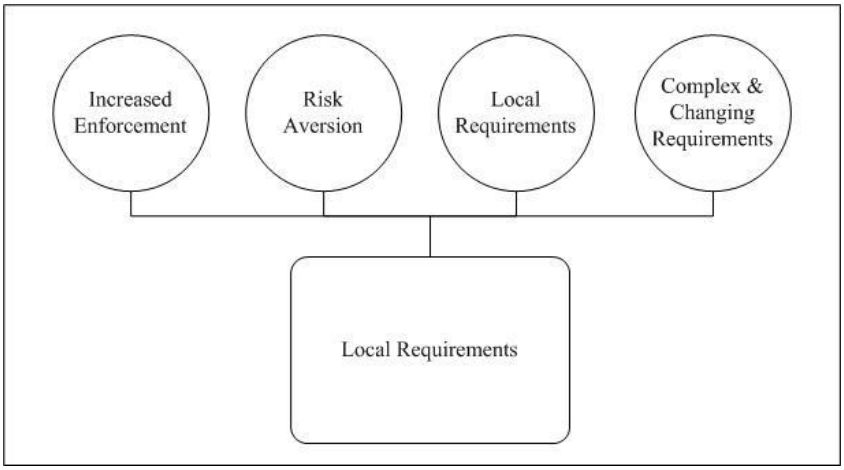

Figure 3. Selective Coding Process

CONCLUSION

All research has limitations. If viewed in the correct light, the identified limitations are opportunities to determine how they can be overcome to allow for future research and provide guidance to institutions.

By using the Glaser and Strauss Grounded Methodology to define the important aspects of the interactions between actors, critical dimensions of the underserved cooperation between research administrators and investigators were identified.

The primary limitation reflects the population of the Grounded Theory model. The groups interviewed were subject matter experts in the application of regulations both nationally and locally at their individual institutions. The sample intentionally did not include regulators or legislators. The regulations served as proxies for the population of regulators. However, there is room for improvement. A more focused study that looks at the process of regulation creation, including population and methods, would provide further insight.

The primary policy suggestion involves investment in training participants. This change starts at the local institutional level where individual investigators and IRB staff can work together to address local

requirements that may stem from institutional mandates or state and federal requirements; any tension that is present disrupts the process. This teamwork, when properly functioning, should be transparent. However, if the necessary cooperation is not present, problems may arise. The interviews conducted in this study indicate that collaboration is desired but often difficult to achieve. Each institution should strive to foster an environment of cooperation and communication. Regardless of whether the model suggested in this work is applied or not, costs should be minimal when compared to other solutions and training would be beneficial.

The theme of Desire to be seen as a professional was very prevalent in the survey, and appeared to stem from the desire of research administrators to be seen as an important part of the team that supports researchers. The second policy suggestion suggests a path for research administrators who have demonstrated dedication to the field. The new degrees offered by higher education institutions allowing research administrators to obtain master's degrees in research administration and the CRA accreditation are excellent avenues for those looking to demonstrate professionalism to the field. The Certified Research Administrator is similar to other professional certifications, such as the Project Manager Professional (PMP), and requires continuing education credits to maintain.

The real-world difficulty of blending the needs of both staff and faculty demonstrates why the topic of research administration is an important subject of ongoing discussion. As shown in this study, the qualitative relationships defined through Grounded Theory substantiate the finding that research administrators, who seek to play a positive role, desired teamwork in supporting investigators as they conduct complex human research studies.

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APPENDIX

1) Can you tell me your age range?
   - 25 –35
   - 35 –45
   - 45 –55
   - 55 Above
2) Can you describe your role in your institution?
   - Office Staff
   - Departmental Staff
   - Management
   - Executive
   - Researcher
3) What is your highest degree earned?
4) How would you describe your role in Research and/or Research Administration?
   - Scientist / Researcher
   - Research Administration
   - Both (such as a Board member)
5) How long have you been working in Research or Research Administration?
6) Tell me about your experiences with Research Administration.
7) How do you explain your job to people outside of Research or Research Administration? (Example: Friends or Family)?
8) What is the best part of Research Administration?
9) What is the most trying or hardest part of working through Research Administration?
10) Over your career do you feel that there are more regulations? Less? About the same?
    Follow-up: Can you explain?
11) If more: Do you ever feel that these regulations "get in the way" or hinder research?
12) Do you understand the abbreviations Grants, COI, IACUC, IRB?
13) Do you feel that research scientists understand the regulations they must uphold? (Grants, COI,IACUC, IRB)
    Follow-up: Can you explain?
    Follow-up: Which ones cause the most confusion?
    Follow-up: Which ones are the easiest to understand?
14) Do scientists (or their team members) ever voice concern or complain about the regulations, policies or expectations?
    Follow-up: Can you recall which regulations or polices stand out as receiving the most criticism?
15) Do you believe scientists and Research Administrators work together or against each other?
16) How would you improve current regulations or polices for any of the departments under Research Administration? Research Administration as a whole?

17) Do you have any Research Administration stories or additional information you want to share?

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