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An assessment of IRB member values using the IRB Researcher Assessment Tool

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AN ASSESSMENT OF IRB MEMBER VALUES USING THE IRB RESEARCHER ASSESSMENT TOOL

by

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Abstract

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This study employed the IRB Researcher Assessment Tool (IRB-RAT) to better understand values held by IRB members at Rowan University, and piloted the use of the IRB-RAT in this institutional context. A sample of Rowan University IRB affiliates, including administrators and members ($N = 11$), provided ratings related to their "ideal" and "actual" IRB on this 45-item questionnaire, addressing eight areas of IRB performance. Analyses included mean calculations, calculations of mean difference, and comparisons to those provided in a national validation sample for the measure. Results indicated that, by comparison to a national validation sample, Rowan University IRB members tended to view the performance of their IRB as being more closely aligned to their vision of an ideal IRB than as seen in the evaluations of IRB affiliates in related literature. In addition, a relatively high level of concurrence was observed with regard to member ratings across items. Findings indicate the need for more work in the area of IRB performance measures, and highlight the unique information generated by using the IRB-RAT in this particular institutional setting. Further, findings highlight the need for a greater number of studies that use IRB performance measures, to enable IRB researchers to understand how these measures may be differentially useful in a variety of institutional and IRB contexts.

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Chapter I

Introduction

At universities and other research institutions, Institutional Review Boards (IRBs) serve as the main regulatory body to ensure that human subjects research is conducted ethically and in accordance with federal policy. However, relatively little research has been conducted to critically examine or evaluate IRBs, and wide variations can exist in IRB function and efficacy from institution to institution. As a result, learning more about these regulatory bodies is both a critically important and challenging task (Abbott & Grady, 2011). Nonetheless, in examining the structure and function of IRBs using validated methods of assessment, it is possible that meaningful conclusions can be drawn about areas for future improvement in efficacy and practice. In turn, this study utilizes the IRB Researcher Assessment Tool (IRB-RAT), a measure designed for IRB self-study, to learn more about the values of members of the Rowan University IRB. In doing so, this and other studies can help to build a knowledge base that will help to support the establishment of more complex and comprehensive IRB research in the future.

Statement of the Problem

Research regarding IRBs is both limited in nature and challenged by natural variations that exist in the way that IRBs may wield power, interpret regulations, manage membership and staffing, and conceptualize efficiency (Abbott & Grady, 2011). As a result, while it is imperative that more research be focused on evaluating IRB functioning and efficacy, measures and methods for evaluating IRBs are limited in nature. As a result, additional work is needed to grow the understanding of what issues and areas of concern

are most important to IRBs, specifically in individual institutional contexts. In addressing these concerns in specific institutional populations, the IRB-RAT is one measure that has been used among IRB member and investigators, in order to learn more about IRB performance and stakeholder values. However, previous evaluations of the Rowan University IRB have not focused on stakeholder values, nor has the IRB-RAT been piloted to understand how the measure might perform in this particular institutional setting. As a result, more comprehensive assessment is needed to understand the way in which stakeholders, such as IRB administrators and members, may conceptualize qualities of both their existing and ideal IRB within this institutional context.

Purpose of the Study

The purpose of this study is to initiate the use of an existing measure of IRB quality (Keith-Spiegel, Koocher, & Tabachnick, 2006) among administrators and members of the Rowan University IRB. In doing so, this work seeks to draw upon methodology employed by Hall et al. (2015), using data generated by respondents to provide information that may help to identify areas for targeted performance improvement for the Rowan University IRB. This study is also aimed at providing the Rowan University IRB with more comprehensive information regarding member evaluations of performance, which may be useful in guiding future decisions with regard to staffing, membership, practices, and policies.

Significance of the Study

In considering the existing dearth in IRB-related research, this study recognizes that it may be important to consider IRB evaluation on a case-by-case basis, as a means

of growing this body of knowledge in an incremental fashion, thereby guiding future efforts that may require IRB policy and practice reforms (Abbott & Grady, 2011). As a result, this study provides knowledge regarding the values of existing IRB members and administrators at Rowan University, setting a foundation for further IRB-related assessment in this particular institutional setting. In addition, by replicating prior work involving IRB quality assessment and improvement plans, such as that conducted by Hall et al. (2015), this study will add the perspective of another institutional setting to the IRB performance assessment literature.

Assumptions and Limitations

This study assumes that the limited number of IRB members and administrators who have acted as respondents have provided data that accurately represents their perceptions of the Rowan University IRB, but that this data will not capture the ideas of all its members, necessitating more comprehensive future work. In turn, this study is limited by a small sample size, and may lack diversity with regard to the varied professional backgrounds, levels of experience, and disciplinary backgrounds considered important in the context of the IRB as a whole. Further, due to the possible sensitive nature of the information sought in this research and the assumption of some participatory reticence of respondents, some degree of response bias may be anticipated to limit these results. In addition, due to experience interacting with the Rowan University IRB as an investigator in the past, and my concurrent experience as an unpaid intern of the Rowan University IRB, some researcher bias may be present.

Operational Definitions

1. IRB: The Institutional Review Board, a regulatory body comprised of institutionally and non-institutionally affiliated members who reflect disciplinarily, professionally, and otherwise diverse backgrounds, and who are tasked with the review of proposals involving human subjects research. IRBs ensure the ethical treatment of human research participants, uphold regulations set by the U.S. Office for Human Research Protections, a division of the Department of Health and Human Services, and help to troubleshoot quality research design.
2. Rowan University IRB: The Rowan University Office of Research Compliance supports two IRBs, and each board represents distinct institutional affiliations: one board represents the IRB for the main Glassboro campus and Cooper Medical School of Rowan University (CMSRU), and the other board represents the IRB for the Rowan School of Osteopathic Medicine (SOM). In recognizing the common administrative leadership shared by both IRBs, and to help protect participant privacy, data from all respondents, regardless of campus IRB affiliation, has been aggregated for the purposes of this study. At the time of survey administration, a total of 26 members comprised the Rowan University IRBs, including both Rowan SOM and Glassboro/CMSRU boards. Each of the Rowan University IRBs meet monthly, utilizing a digital interface, known as eIRB, for the review of protocols.

Research Questions

1. How do Rowan University IRB member values align with regard to their assessment of their "actual" and "ideal" IRB?
2. How do Rowan University IRB member ratings provided on the IRB-RAT align with national validation sample data, overall?
3. What, can be learned about the use of the IRB-RAT as a self-study measure in this particular institutional context, particularly with regard to its potential for future use?

Overview of the Study

Chapter II consists of a review of relevant literature, compiling scholarly work that guides the understanding of IRB-related research used in this study. The review in this study pertains to the structure and function of IRBs, relevant research regarding IRB members and those who interact with the IRB for research purposes, and the methods and means by which past research has studied IRBs.

Chapter III describes the methodologies used in this study. In describing methods used, information is included about the location of the study, sampling, population characteristics, data gathering procedures, and data collection tools. In addition, the section concludes with a description of data analysis procedures.

Chapter IV describes the findings and results of this study, including tables for summarizing pertinent data.

Chapter V summarizes and discusses the major findings of this study, including conclusions and recommendations for further research

Chapter II

Review of Literature

Institutional Review Boards (IRBs; commonly referred to as Research Ethics Committees outside the U.S.) are important gatekeepers of the research process, working to ensure that all research involving human subjects is safe and ethically sound, and conducted with a concern for human welfare (Shore, 2014). Yet, while IRBs carry substantial legal and ethical obligations in working for the advancement of science and medicine, these boards often must operate under serious funding and resource limitations (Klitzman, 2015; Woodward, 1999). Further, tensions between IRBs and researchers can be high, as investigators may perceive their IRBs as bureaucratic entities, unjustifiably delaying and restricting their research (Klitzman, 2011, 2012, 2015). As a result, while 84% of IRB members felt that their board was generally efficient, less than two-thirds of investigators agreed, providing some insight to the strains between IRBs and the researchers they serve (Klitzman, 2015).

Given the frequent constraints placed upon IRB members and administrators, and the challenging relationship between IRBs and investigators, evaluating the quality of IRBs and their work has become an increasingly important priority (Andrews et al., 2012; Brozek, 2013; Hall et al., 2016). However, while some prior work has begun to examine IRB quality, IRB-related research is nonetheless quite limited (Klitzman, 2015), and IRB quality remains an esoteric concept, requiring further study and evaluation to fully understand (Abbot & Grady, 2011). In addition, research that focuses upon or critically evaluates IRBs is considered to be quite limited in nature, as evidenced by Abbott and Grady (2011) in this single case of a systematic review of IRB-related empirical

literature. The idiosyncratic nature of IRBs, which differ in size and available resources from institution to institution, further complicates the generalizability of IRB-related research (Abbott & Grady, 2011). As a result, this literature review is reinforced by the perspective that institutional context should serve as a motivation and justification for the repetition of prior work on IRB quality. As such, this literature review will describe the contextual and historical basis for IRB performance, discuss relevant challenges to IRB performance, detail the conceptual framework for the study of IRB quality, and describe the way in which studies of IRB quality have or could motivate quality-enhancing reforms at the level of individual IRBs.

IRBs: Context and Function

With respect to their structure and function, today's IRBs bear the heavy influence of historical precedent (Hart & Belotto, 2010). IRBs were developed in response to the formalization of research ethics over the past century; as such, the historical context within which IRBs were formed is still evident in the way that IRBs appear today (Hart & Belotto). As a result, a series of historical developments precipitated the modern-day IRB, which owes its composition and structure to the mandates of national regulations, which were derived from the formalization of ethical principles (Hart & Belotto, 2010). Many important turning points in the development of standards for human subjects research have occurred in response to instances of egregious mistreatment of human research subjects, necessitating the formation of committees that could enforce and carry out a set of ethical standards for research (Hart & Belotto, 2010).

In 1947, at the International Military Tribunal Trial at Nuremberg, Germany, a U.S. court indicted 23 Nazi physicians who had conducted pseudoscientific experiments upon concentration camp prisoners, resulting in injury, disfigurement, and death (Hart & Belotto, 2010). These egregious human rights violations spurred the development of the Nuremberg Code, a document establishing standards for the ethical treatment and informed consent of research subjects (Hart & Belotto, 2010). While the Nuremberg Code advanced international standards for human research protections, it did not include any mandates for research ethics committees that might enforce these standards (Shore, 2014). In response, the U.S. National Institutes of Health created Clinical Research Committees for the review of research in the 1950s (Hart & Belotto, 2010), and in 1966, the Public Health Service (PHS) began requiring independent reviews for research proposals in the U.S. (Shore, 2014). Nonetheless, these policies failed to include specific standards for research review or the composition of review committees (Shore, 2014).

In 1972, public attention turned to the exposé of the 40-year long, PHS-sponsored Tuskegee Syphilis Study, in which researchers deprived syphilitic patients of medical treatment and left these patients unaware of their illness (Hart & Belotto, 2010). Ensuing public outcry motivated the shutdown of this trial, and led to the development of more stringent government oversight for research (Hart & Belotto, 2010). The National Research Act was developed in response, leading to the publication of *The Belmont Report* in 1979, which described three principal ethics in research (Shore, 2014). These three principles—Beneficence, Justice, and Respect for Persons—continue to be recognized as basic tenets of sound, ethical research today (Hart & Belotto, 2010).

The Belmont Report also served as a major influence in the development of the Federal Policy for the Protection of Human Subjects—45CFR46, subpart A, known as the Common Rule—which was established in 1991 (Shore, 2014). This policy mandated the formation of IRBs as they exist today, including federal standards for IRB composition and rules regarding the process by which IRBs review protocols (Shore, 2014). As it fundamentally relates to the IRB, the Common Rule establishes that any U.S. institution receiving federal funding and which sponsors research must form an institutional board to screen research proposals, to ensure that no human subjects will be harmed (U.S. Department of Health and Human Services, 2009). As such, the Common Rule acts to legally enforce the establishment of IRBs as a prerequisite for engaging in human subjects research (U.S. Department of Health and Human Services, 2009). Today, the Office for Human Research Protections (OHRP) maintains oversight of over 5,500 IRBs nationwide, ensuring that IRBs manage their boards and conduct their reviews in accordance with the Common Rule (Pritchard, 2011).

Concerning IRB member composition, the Common Rule contends that all IRBs be comprised of at least five board members, including: at least one member whose interests are mainly scientific, at least one member whose interests are mainly nonscientific, and at least one member who lacks institutional affiliation (Pritchard, 2011), possessing neither scientific nor nonscientific interests (Hart & Belotto, 2010). In addition, members must be of both sexes, come from a variety of professional backgrounds, and the board must include members who are knowledgeable of the interests of any groups of vulnerable participants who are regularly used as research subjects, such as children or prisoners (Grady, 2015). Due to these requirements,

institutions that engage in research across a greater variety of disciplinary areas or in greater volume may choose to support boards with greater numbers of members or may even decide to support multiple IRBs (Klitzman, 2015).

In the time since the enactment of the Common Rule, research review has evolved to encompass new responsibilities for researchers and IRB members (Hart & Belotto, 2010). Members of IRBs today face a research climate that has changed substantially in the decades since Common Rule took effect (Klitzman, 2015), and thus must often carry out additional duties that go beyond those explicitly required by the Common Rule (Grady, 2015). For example, concurrent with the rise in industry-funded medical research trials (Klitzman, 2015), today's IRBs may critically evaluate researcher conflicts of interest (Grady, 2015) and in some cases undertake time-consuming investigations even where researchers may declare no conflict of interest to exist (Klitzman, 2015). As a result, IRB members' duties often go beyond the review of protocols alone; in addition, they may also take time to educate investigators on research ethics, stay on top of ever-changing local and federal laws that may apply to the conduct of research, and check in on approved trials to ensure that scientists report any modifications or reportable events (Grady, 2015).

Challenges to IRB Performance and Interaction Quality

The relationship between IRB members and the investigators they serve is of significant concern to IRB researchers and the academic community at large featuring as a central topic of interest in several studies (Dougherty & Kramer, 2005; Kramer, Miller, & Commuri, 2009; Hamilton, 2002; Klitzman, 2012). Relationships between IRBs and investigators may vary significantly from institution to institution, with interactions

between researchers and their IRBs varying from highly cordial to contentious (Klitzman, 2015; Kramer et al., 2009). As previously noted, significant discrepancies often exist in how IRB members and investigators may rate or perceive IRBs, with results of these types of studies usually indicating higher levels of IRB disapproval among investigators compared to members (Klitzman, 2015). Nonetheless, some studies, such as the work of Stryjewski et al. (2015) have indicated high levels of investigator approval (97%) with the way in which IRBs work to protect human subjects. However, this work in particular is limited by low response rates, suggesting the potential role of response bias in influencing the results seen in this and other work in which IRB performance is rated by members and investigators (Stryjewski et al., 2015).

IRB member challenges. A variety of challenges may impact the degree to which IRB quality is reflected in the practices of IRB members. In particular, one influence upon IRB member behavior that has been considered in some prior work is the role of common psychological factors (Candilis et al., 2012; Pritchard, 2011). In assessing patterns of dialogue in IRB meetings, Candilis et al. (2012) note that members who were not designated reviewers or chairs tended to speak minimally or not at all during meetings. This suggests that psychological patterns of consensus, such as groupthink, may to some degree characterize IRB decisions (Candilis et al., 2012). In addition, Pritchard (2011) suggests that, when faced with a study about which the IRB member possesses little professional knowledge to guide their decision-making, it may be likely that risk-averse decision-making patterns may predominate.

Further, IRB member performance may be influenced by some challenges related to the degree to which members understand or perceive their power and influence.

Dougherty and Kramer (2005) highlight the narrative of one individual whose experience as both a researcher and as an IRB member cultivated frustrations with the bureaucratic power of the IRB. However, Klitzman (2011) found that, in considering their power, many members and chairs were skeptical that their IRB held a great degree of power, given that their work could be scrutinized by the federal government, a comparatively more powerful entity, at any time. Furthermore, IRB members and chairs tended to perceive their power as limited, given that their role was to follow a standard process in evaluating all research, considering bias to be a minimal influence in their review process (Klitzman, 2011). In addition, given that IRB members felt themselves powerless to defend their decisions or speak out openly against criticisms of their work, they felt themselves to hold little power in the face of investigators—whom, by comparison, they felt could disparage the IRB publicly at any time (Klitzman, 2011).

In addition, another area in which IRB members may be limited in their performance is in the review of protocols that may fall outside their personal areas of expertise (Klitzman, 2015). Mhaskar et al. (2015) found that a majority of IRB members surveyed possessed insufficient subject area knowledge needed to understand the protocols under their review. Further, most IRB members lacked pertinent knowledge regarding study design for protocols that they later submitted for approval, suggesting that IRB members may sometimes make decisions in the absence of adequate knowledge (Mhaskar et al., 2015), a limitation of IRB performance similarly noted by Sirotin et al. (2010). More broadly, IRBs often exhibit significant limitations in the financial resources they receive from their institution (Sirotin et al., 2010), a resource limitation made perhaps most apparent in that many IRB members serve as unpaid volunteers (Saver,

2005). Further, members may receive little or no formal training before joining the IRB (Klitzman, 2015), and often must complete their duties as IRB members in addition to satisfying the responsibilities associated with their typical workload (Sirotin et al., 2010).

Investigator challenges. As the narratives highlighted by Klitzman (2015) demonstrate, the relationship between IRBs and investigators is two-way, with investigators sometimes posing challenges to the efficient performance of the IRB. Investigators' negative attitudes toward IRBs may be hostile (Klitzman, 2011), or be exhibited more subtly, by the tendency to caricature IRBs, complain, or feign cooperation (Dougherty & Kramer, 2005), submitting protocols that may fail to fully represent the full extent of a research design (Klitzman, 2015). Further, some IRB members interviewed by Klitzman (2015) noted that they deal regularly with researchers who submit shoddy protocols, which may be poorly written or contain missing parts that are needed to fully understand and review the study. In turn, IRB members expressed a great deal of frustration with these types of protocols, noting that shoddy protocols required an inordinate amount of time to review and lengthy communication with researchers to rectify (Klitzman, 2015). In general, these investigators were usually thought to be unfamiliar with common standards for protocol writing, lacking education or understanding of the research review process (Klitzman, 2015).

Theoretical Perspectives & IRB Quality

Grady (2015) suggests that instances of IRB "mission creep" may impact the quality of the research review process, and may be evidenced by the expanding list of regular duties that IRB members may carry out beyond the regular review of protocols. Nonetheless, IRBs may be compelled to extend their activity beyond protocol reviews in

order to carry out their charge of maintaining thorough oversight (Grady, 2015), citing the need to adapt to significant changes in the way that researchers structure, carry out, and receive sponsorship for their studies (Klitzman, 2015). In turn, while investigator perceptions of IRBs vary considerably (Keith-Spiegel, Koocher, & Tabachnick, 2006), IRBs vary substantially too, with considerable differences in size, member composition, and workload (Klitzman, 2015). As a result, in the systematic review of IRB research carried out by Abbott and Grady (2011), the investigators highlight the need to further refine definitions of IRB quality, in order to reach consensus on how to measure and draw important conclusions on the quality of IRBs.

Measuring & conceptualizing IRB quality. Importantly, Keith-Spiegel et al. (2006) are credited with creating one of the only existing measures for IRB quality (Brozek, 2013), and as such, this serves as an important model for understanding how IRB quality may be conceptualized. This measure, the *IRB Researcher Assessment Tool* (IRB-RAT), is predicated upon theoretical understandings of organizational justice. Keith-Spiegel et al. (2006) contend that, when IRB efforts to protect human subjects or interact with researchers are incompetent, these lapses are procedural in nature, reflecting an inadequate or unjust process.

As a result, Keith-Spiegel et al. (2006) theoretically situate their measure of IRB quality around procedural justice, hypothesizing that, when IRBs achieve higher levels of procedural justice, their decisions and interactions with researchers are of higher quality. In turn, they suggest that, when IRBs adhere more closely to ideals of procedural justice, investigator dissatisfaction with their IRB may be lower (Keith-Spiegel et al., 2006). Procedural justice, as a concept related to organizational dynamics, is concerned with the

evenhanded delivery of a fair and regular decision-making process, which works against the influence of personal biases (Keith-Spiegel et al., 2006). In the context of IRBs, procedural justice ensures that investigators are listened to closely and treated with dignity and respect, and that their protocols are reviewed systematically, with regard for due process (Keith-Spiegel et al., 2006).

Though Keith-Spiegel et al. (2006) suggest a procedural justice framework for understanding the quality of IRBs, this research primarily emphasizes the benefits that a procedurally just IRB process confers to investigators, rather than subjects. Nonetheless, procedural ethics frameworks have also been applied more broadly to other dimensions of research; for example, procedural ethics form the basis of standard research ethics training in the biomedical sciences (Hunt & Godard, 2013). This understanding of research ethics also applies to the responsibility that researchers have to emphasize fairness, consent, and disclosure in their treatment of human subjects (Guillemin & Gillam, 2004). Guillemin and Gillam (2004) also suggest that, for researchers, the process of writing, submitting, and obtaining approval for their protocol is in and of itself a reflection of the investigator's participation in an ethical process, and therefore is suggestive of procedural ethics in practice. The historical development of ethical standards for research, and in turn, IRBs, has been concurrent with the development of the formalized understanding of procedural justice over time (Guillemin & Gillam, 2004). As a result, Keith-Spiegel et al. (2006) work from a theoretical perspective that emphasizes procedural justice in the exchanges between investigators and IRB members, using this as a mark of IRB quality in the role these committees play in regulating the research process.

Measuring & Improving IRB Performance

Despite the need to evaluate IRBs for quality to foster improvements in the way in which both investigators and IRB members engage in the research review process, available measures for IRB performance are somewhat uncommon (Brozek, 2013). Thus, the IRB-RAT, an IRB performance assessment instrument, serves as an important, if singular example of the way in which IRB performance can be defined and measured (Keith-Spiegel et al., 2006). In creating this 45-item instrument, Keith Spiegel et al. (2006) considered the most significant priorities for IRB performance noted by a large sample of surveyed investigators. Individual items consist of a statement adjoined by a 7-point Likert scale, with which respondents compare how the statement matches their ideal IRB as well as their actual IRB (Hall et al., 2015). As such, the IRB-RAT serves as a validated and internally normed measure for IRB quality (Hall et al., 2015), making it unique in this regard compared to other potential methods for assessing IRB performance, such as through qualitative evaluations.

In the time since its creation, the IRB-RAT has been utilized in studies assessing IRBs internationally, and in a variety of institutional settings (Chenneville et al., 2014; Hall et al., 2015; Reeser et al., 2008). In using data from this measure to make recommendations for quality improvements, Hall et al. (2015) serve as a particularly noteworthy example. In gathering investigator and IRB member ratings on the IRB-RAT, Hall et al. (2015) then used a system of relative ranking to distinguish those survey items most frequently rated as constituting highly valued reforms from those ranked less important by respondents. While it is not clear whether targeted recommendations for improvement were provided to the investigators' IRB following this research, this study

helps to indicate how the IRB-RAT might be used to better understand the priorities of investigators and members with regard to the quality of their respective IRBs (Hall et al., 2015).

IRB improvement. One outcome of research on IRBs has been the discovery of potential areas for IRB performance improvement. Saver (2005) suggests that the evolution of the research community has outpaced the innovation of the IRB. As such, in order to maintain stride with the constant growth of research, Saver (2005) contends that IRB reformers may be well-advised to consider the model provided by corporate boards. For example, despite common IRB pleas for greater membership to offset their ever-increasing workload, Saver (2005) points to the example of corporate boards; without more fundamental reforms, corporate boards often fail to become more efficient simply by adding more members. Like corporate boards, who have limited time and often make decisions with limited information, Saver (2005) suggests that IRBs would be more effective at ensuring the protection of human subjects if they spent less time reviewing the minute details of paper protocols, and instead allocated some time to conduct researcher observations and interviews with participants.

In concurrence with Saver (2005), Grady (2015) agrees that IRBs require reform in order to keep pace with the research community, whose demands upon the IRB appear to be ever increasing. In the future, Grady (2015) suggests that IRBs use a pre-review process to ensure that significant methodological issues are addressed and corrected before a proposal reaches the IRB, in order to increase efficiency. In addition, some institutions have adopted additional models that require greater accountability of researchers' departmental chairs, requiring a preliminary departmental review before

protocols reach the IRB (Grady, 2015). In addition, it is important to note that, although data are presently limited to inform improved practice among IRBs, NIH-supported trials are underway with the specific goal of improving IRB practice and driving needed policy-reform (Grady, 2015).

Klitzman's (2015) in-depth, interview-based investigation of IRB members and chairs found that reforms are needed on both sides of the review process in order to bring more efficiency and effectiveness to protocol reviews. For example, the IRB review process, which was developed with the biomedical sciences in mind, could be modified to offer a different type of review for social science researchers, to better meet their unique needs (Klitzman, 2015). In addition, there currently exists no external appeals process for researchers to challenge the decisions of their IRBs (Klitzman, 2015). Creating an external appeals process would help to identify and rectify IRB decisions that may be based upon biases toward certain types of research, or which may be motivated by personal differences between IRBs and researchers (Klitzman, 2015). In addition, while some researchers have extolled the benefits of centralized IRBs (CIRBs) for multisite studies (Schnipper, 2017; Wechsler, 2007), Klitzman (2015) suggests that more consideration is needed to ensure that CIRBs and study sites can engage in open communication before, during, and after a trial is conducted.

IRB reforms in action. Due to the idiosyncratic nature of institutions and their review boards, some of the most impactful reforms to IRBs may be those that can be enacted at the institutional level, as indicated in the example provided by Andrews et al. (2012). Andrews et al. (2012) proposed and implemented changes that separated their institution's four IRBs into eight smaller committees, and made board meetings more

frequent, but shorter in duration. As a result of these changes, Andrews et al. (2012) note that turnaround times for submitted protocols decreased by 46%, and board members spent less total time in IRB meetings per month, despite meeting more frequently. In doing so, IRB members had fewer items on each agenda to review prior to meetings, allowing members to be more prepared for meetings and have higher quality discussions on agenda items (Andrews et al., 2012). This noteworthy example provided by Andrews et al. (2012) may lack generalizability to most institutions, whose IRBs may be structurally and functionally different from those at the institution described in this study. However, this example may indicate the possibility for IRBs to increase quality by restructuring their boards and meetings to suit institutional needs and priorities.

Summary of the Literature Review

This literature review provides further insight to IRBs as they exist today, with regard to their purpose, function, assessment, and quality. IRBs perform an important role in managing ethical dimensions of the research process, but IRB members occupy increasingly complex roles as research innovation and volume increases. As a result, assessing IRB quality is an important priority for understanding where our IRBs may succeed or fail in serving investigators and ensuring the protection of human research subjects. In turn, this review of the literature is presented from the perspective that, with careful consideration of performance data, IRBs may be able to positively impact the quality of their services and make needed reforms to ensure that their work continues to be of the highest standard possible. In working toward this understanding, this literature review underscores the importance of building the current body of research on IRB quality as necessitated by two major limitations in the existing body of work on IRBs and

IRB quality: first, research on IRBs is noted to be generally limited in nature (Abbott & Grady, 2011; Klitzman, 2015), suggesting that the replication of prior studies would advance the field, and strengthen the validity of prior findings, rather than being merely repetitious. Secondly, as a result of broad limitations in IRB research, the role of the institutional context in influencing IRB quality needs to be further explicated, through the repetition of IRB quality studies at a wider variety and number of institutions.

Chapter III

Methodology

Context of the Study

This study was conducted at Rowan University, involving members from its main campus, in Glassboro, NJ, as well as those from the Rowan SOM campus in Stratford, NJ, and the CMSRU campus in Camden, NJ. Rowan University is classified as a public, doctoral research university with R2 status, denoting a high level of research activity (Carnegie Classification of Institutions of Higher Education, 2019). Rowan University has two IRBs, each with its own set of members and some administrative overlap. One of these IRBs is located at the Rowan University School of Osteopathic Medicine (SOM), in Stratford, NJ, and is dedicated to the review of research on that campus only. Rowan University's other IRB is located in Glassboro, NJ, and this IRB reviews research protocols from the main Glassboro campus in addition to protocols from the Cooper Medical School of Rowan University (CMSRU), located in Camden, NJ. Both IRBs hold monthly meetings in their respective campus locations.

This study was conducted to learn more about the Rowan University IRB as it functions as a whole, and therefore, both IRBs were of interest in this study. The Rowan University Glassboro/CMSRU IRB consists of 13 members, including 12 voting members and one non-voting member. This IRB contains both scientist and non-scientist members, who represent a variety of disciplinary backgrounds and research experiences, including those with expertise in various areas of the social and medical sciences. In addition, this Rowan University IRB includes two community representatives among its

members. This IRB is led by a faculty chairperson, and is also supported by a research compliance specialist and chief compliance officer.

The Rowan SOM IRB consists of 13 members, which include 12 voting members and 1 non-voting member. Given the context of medical research at the Rowan SOM campus, the Rowan SOM IRB consists of members with professional roles as physician scientists, scientists from other related disciplinary backgrounds, and non-scientist members.

Population and Sampling

The target population for this study included members and administrators affiliated with the Rowan University IRBs located on the Glassboro, NJ and Stratford, NJ campuses. Given the specialized nature of the survey, this subset of the campus population was identified as the most likely group of individuals to possess knowledge regarding the specific functioning of the Rowan University IRB. The study population included any of these IRB members and administrators who were interested in participating in this study. Purposive sampling was used to select those directly affiliated with Rowan University IRB(s) only, as displayed in the IRB committee listings on the Rowan eIRB website at the time of survey administration. This prospective sample included a total of 26 individuals, including 23 IRB members and 3 administrators.

Instrumentation

Data were collected using the IRB-RAT (Keith-Spiegel & Tabachnik, 2006), a validated and normed measure of IRB quality (Hall et al., 2015). This instrument was selected because is currently the only widely available, validated measure of IRB quality, and has been used in prior studies (Brozek, 2013). The IRB-RAT consists of questions

designed to address eight major areas of IRB performance, including: procedural justice; IRB outreach; interpersonal justice; IRB formal functioning, structure and composition; pro-science sensitivity; bias; competence; and upholding the rights of human participants. This measure consists of 45 statements regarding IRB performance. Respondents use a 7-point Likert scale to rate how well each item describes their *ideal* IRB, followed by an identical 7-point scale to report how that item describes their *actual* IRB. The measure was published as an open access resource, with authors granting full permission for the measure to be used, with attribution.

Data Collection

The Rowan University IRB approved all procedures and documents associated with this study prior to data collection (Appendix A). To minimize any possible conflict of interest, an IRB member recused from study participation reviewed and approved the study protocol. Prospective subjects who received the survey included 27 affiliates of Rowan University IRBs. Participants were recruited for the survey through emails sent between the dates of February 8th, 2019 and March 20th, 2019. The email consisted of an outreach letter, which explained the study, along with a link to the survey in Qualtrics, an online survey platform (Appendix B). After reading an IRB-approved consent document on Qualtrics, participants verified their age (18 or older) and willingness to participate in the survey, after which point they could choose to complete the survey, skipping any questions they did not wish to answer. Over the month that the survey remained open, respondents received three weekly reminders to complete the survey.

Data Analysis

Following the survey administration period, all data was downloaded from Qualtrics into Statistical Package for the Social Sciences (SPSS) software. For each survey item, sample averages were computed for ratings provided on the ideal and actual IRB. In addition, the average difference between the actual and ideal IRB ratings was computed.

Chapter IV

Findings

Profile of the Population

The target population for this study included all members and administrators affiliated with the Rowan University IRB, including those representing the IRB for the main Glassboro, NJ campus and CMSRU, and those representing the Rowan SOM IRB in Stratford, NJ. At the time of survey administration, this included a total of 26 Rowan University IRB affiliates. Of this population, 11 respondents completed the survey, yielding a response rate of approximately 42%. Because the study targeted such a limited target population, demographic information was not collected, in order to protect participant privacy and avoid the inadvertent collection of potentially identifying information. As a result, it is unclear what, if any characteristics may distinguish those who responded to the survey from those who chose not to, including campus affiliation and disciplinary background.

Analysis of the Data

Research question 1. How closely do Rowan University IRB member values align with regard to their assessment of their "actual" and "ideal" IRB?

Table 4.1 displays the mean score for each IRB-RAT item, including the mean difference for actual minus ideal ratings for each item.

Research question 2. How do Rowan University IRB member ratings provided on the IRB-RAT align with national validation sample data, overall?

Table 4.1 also displays ideal IRB ratings from the national validation sample.

Table 4.1

Mean Ratings of Items from the IRB Researcher Assessment Tool, Including Ideal Ratings from the National Validation Sample and Current Sample, and Actual Ratings from the Current Sample

	Ideal IRB		Actual IRB	Actual–ideal IRB
Item text	National Validation Sample	IRB member/ staff	IRB member/ staff	IRB member/ staff
1. An IRB that reviews protocols in a timely fashion	6.43	6.64	5.82	-0.82
2. An IRB whose members do not allow personal biases to affect their evaluation of protocols	6.17	6.82	6.55	-0.27
3. An IRB that does a good job of upholding participants' rights while facilitating the conduct of research	6.10	6.36	6.00	-0.36
4. An IRB that does not use its power to suppress research that is otherwise methodologically sound and in compliance with federal policy whenever it perceives potential criticism from outside the scientific community.	6.08	6.36	6.18	-0.18
5. An IRB with members who are very knowledgeable about IRB procedures and federal policy	6.01	6.09	5.80	-0.29
6. An IRB that conducts a conscientious and complete review of protocols	5.86	5.40	5.50	0.10
7. An IRB that views protection of human participants as its primary function	5.80	6.55	6.60	0.05
8. An IRB that responds in a timely manner to investigators' inquiries about its processes and decisions	5.80	5.73	6.00	0.27

Table 4.1 (Continued)

Item text	Ideal IRB		Actual IRB	Actual–ideal IRB
	National Validation Sample	IRB member/ staff	IRB member/ staff	IRB member/ staff
9. An IRB that gives a complete explanation for any required changes to or disapprovals of protocols	5.73	6.09	6.09	0.00
10. An IRB that is willing to work with investigators to find mutual satisfying solutions whenever disagreements exist	5.71	5.18	5.60	0.42
11. An IRB whose members fully understand and act within the scope of their function	5.67	5.64	6.18	0.54
12. An IRB that includes a complete rationale when it denies or mandates changes in a protocol based on criteria that are more stringent than or different from federal research policy (i.e., application of "local standards")	5.59	6.10	6.30	0.20
13. An IRB that views its role as being an investigator's ally rather than as being a hurdle to clear	5.57	6.10	6.30	0.20
14. An IRB that conducts a conscientious, informed analysis of potential benefits weighed against potential risks before making decisions	5.54	6.90	6.60	-0.30
15. An IRB that takes timely and appropriate action whenever scientific misconduct is alleged	5.52	5.80	5.75	-0.05
16. An IRB that is open to reversing its earlier decisions (i.e., willing to carefully listen to investigators' appeals)	5.52	6.30	6.60	0.30

Table 4.1 (Continued)

Item text	Ideal IRB		Actual IRB	Actual–ideal IRB
	National Validation Sample	IRB member/ staff	IRB member/ staff	IRB member/ staff
17. An IRB that invites investigators to present their position whenever a question or concern about a research protocol arises	5.51	6.50	6.50	0.00
18. An IRB that maintains complete and accurate records	5.50	6.10	6.30	0.20
19. An IRB that can competently distinguish exempt from nonexempt research	5.48	6.40	6.10	-0.30
20. An IRB that treats investigators with respect	5.45	6.50	6.40	-0.10
21. An IRB that holds no preconceived biases against particular research topics	5.45	6.70	5.70	-1.00
22. An IRB that requires members to abstain from evaluating protocols whenever a real or apparent conflict of interest arises	5.44	6.80	6.80	0.00
23. An IRB that holds no preconceived biases against particular research techniques	5.43	4.40	5.30	0.90
24. An IRB that is allocated sufficient resources to carry out functions efficiently and thoroughly	5.38	6.00	6.00	0.00
25. An IRB that acknowledges full responsibility for its errors or delays in processing protocols and attempts to correct them as expeditiously as possible	5.33	6.50	4.90	-1.60
26. An IRB that offers investigators information to improve the chances of gaining IRB approval	5.31	6.00	5.20	-0.80

Table 4.1 (Continued)

Item text	Ideal IRB		Actual IRB	Actual–ideal IRB
	National Validation Sample	IRB member/ staff	IRB member/ staff	IRB member/ staff
27. An IRB that recognizes when it lacks sufficient expertise to evaluate a protocol and seeks an outside evaluator	5.28	6.63	6.63	0.00
28. An IRB that is open to innovative approaches to conducting research	5.28	5.90	5.60	-0.30
29. An IRB that applies appropriately flexible standards regarding voluntary and informed consent requirements (e.g., required wording is less demanding for minimal risk research using competent adult participants)	5.23	6.90	5.70	-1.20
30. An IRB that takes timely action when an investigator has violated the specifications of its rulings	5.22	6.80	6.60	-0.20
31. An IRB that ensures that at least one member is knowledgeable about the content domain and discipline of submitted protocols	5.13	6.90	6.10	-0.80
32. An IRB composed of members who arrive at meetings well prepared	5.07	6.90	6.00	-0.90
33. An IRB that shows considerable evidence that the advancement of science is part of its mission	4.82	6.40	6.11	-0.29
34. An IRB that requires that its chair be an experienced investigator	4.75	6.80	6.40	-0.40
35. An IRB that is open and pleasant in its interactions with investigators	4.72	6.70	6.20	-0.50

Table 4.1 (Continued)

Item text	Ideal IRB		Actual IRB	Actual–ideal IRB
	National Validation Sample	IRB member/ staff	IRB member/ staff	IRB member/ staff
36. An IRB whose research compliance officer (or staff member in charge of IRB functions) has a background in conducting research	4.68	5.40	4.89	-0.51
37. An IRB that is empathetic with the difficulties that can present themselves during the design or conduct of research	4.66	6.60	5.50	-1.10
38. An IRB that is composed primarily of highly competent investigators	4.46	6.50	5.50	-1.00
39. An IRB that monitors the progress of each approved research project in line with federal policy	4.39	6.00	5.90	-0.10
40. An IRB that provides a comprehensive training program for its new members	4.34	6.70	6.50	-0.20
41. An IRB that offers consultation during the development of research protocols or grant applications	4.30	5.80	6.20	0.40
42. An IRB that has a diverse membership (i.e., includes women, minorities and both junior and senior members of the institution)	4.07	6.90	6.60	-0.30
43. An IRB that offers investigators opportunities to be educated about federal research policy	4.03	6.33	6.63	0.30
44. An IRB that offers editorial suggestions regarding consent documents and protocols (e.g., typos, grammar, clarity)	3.20	6.10	5.70	-0.40
45. An IRB that is composed of more than one public member	2.68	6.00	6.56	0.56
Overall *M*	4.56	6.27	6.05	-0.13

Chapter V

Summary, Discussion, Conclusions, and Recommendations

Summary of the Study

This study used the IRB Researcher Assessment Tool (IRB-RAT) to learn more about the values of IRB members at Rowan University. The purpose of this study was to use this self-study tool to gain valuable insight from IRB members, and to pilot the measure in this institutional context. Subjects of this study included Rowan IRB members from the Glassboro, NJ campus, Cooper Medical School at Rowan University, and Rowan School of Osteopathic Medicine, including scientists, non-scientists, and administrators. The study was conducted during the spring 2019 academic semester, and consisted of an anonymous online survey sent to subjects by email (Appendix B). A total of 11 respondents completed the survey, yielding a response rate of 42%. For each survey item, sample means were computed for ratings provided on the ideal and actual IRB, and the mean difference between the actual and ideal IRB ratings was calculated.

Discussion of the Findings

Members of the Rowan University IRB provided higher overall mean ratings on items when compared to the national sample. Results of this study also indicate that members' ratings were similar in this respect to those obtained from subsets of IRB members and administrators surveyed by Hall et al. (2015, 2016), which were higher than the national validation sample. The mean (*M)* of scores on all items for respondents' ideal IRB was 6.27, compared to a mean of 4.56 as seen in the national sample. By comparison, the mean rating for the ideal IRB provided by IRB members and staff in the example of Hall et al. (2016) was 6.32; both the ideal mean observed in this study, and

that of Hall et al. (2016) were slightly higher than the mean recorded by Hall et al. (2015), which was 6.09. This indicates that, overall, members of the Rowan University IRB tended to consider all aspects of IRB performance to be more highly important in their ideal IRB than among respondents in the national sample, comparing similarly in this respect to ideal ratings noted in some prior studies. Further, the overall mean (*M)* for member ratings of their actual IRB was 6.05. By contrast, this mean score is higher than the overall mean rating that IRB members provided for their actual IRB in the case of Hall et al. (2015), where the observed mean was 5.38, and Hall et al. (2016), where the overall mean for actual IRB ratings was 5.62. Overall, respondents in this study rated their ideal IRB more highly than their actual IRB, with a mean difference of -0.13. This indicates that members rated the performance of their IRB relatively closely to, and only slightly below the performance they would expect of their ideal IRB.

In addressing Research Question 3, this study piloted the IRB-RAT at Rowan University; as a result, some conclusions may be cautiously drawn about the use of the instrument in this institutional setting. The response rate of 42% may be the result of some participatory reticence on the part of the non-respondent portion of the target sample. Further, it is possible that other methods of survey administration, a different time of survey administration, or different recruitment strategies may have improved response rate. It is also unclear whether or not there may be important factors differentiating survey respondents from non-respondents, which could be important to learn more about in future work. Ultimately, while this survey may provide some potentially useful information regarding the values of IRB members at Rowan University, it is also possible that the usefulness of an objective measure such as this one may be

limited in the context of this particular institution. Given that few validated measures exist for the assessment of IRBs (Brozek, 2013), the need for additional work in this area, including methodological studies, is paramount.

Conclusion

This study of the Rowan University IRB provides some meaningful insights with regard to the values of its members. Overall, IRB members rated all items with relatively high importance, and tended to rate the performance of their IRB as being only slightly below that of their ideal IRB. While comparisons to a national sample help to provide some insight to how these results compare to a validation group, more research is needed to more fully understand response patterns using the IRB-RAT. Importantly, this study piloted the IRB-RAT in an institutional setting where this measure had not be previously used, resulting in a novel advancement in the self-study and assessment efforts of the Rowan University Office of Research Compliance.

Recommendations for Further Practice

In considering this study, the following suggestions for further practice are proposed:

1. As the Rowan University Office of Research continues to advance its customer service focus, assessments that gather feedback from stakeholders—including investigators, members, and others—may provide useful information.
2. In continuing to engage in various forms of assessment, the Rowan University Office of Research Compliance may benefit from a review of study findings, keeping relevant study limitations in mind, and considering targeted areas for future self-study.

Recommendations for Further Research

In concluding this study, the following recommendations for further research are presented:

3. IRB-related research should continue to be conducted in an incremental fashion, such as in unique institutional contexts, in order to provide more information on the use of measures such as the IRB-RAT for the purpose of self-study.
4. If replicated, this study would benefit from a higher response rate, in order to capture the perspectives of as many IRB members as possible.
5. Other methodologies, such as qualitative research, might help to more comprehensively understand the perspectives, values, and experiences of Rowan University IRB members and other stakeholders.
6. Future assessments might seek to gather feedback from investigators, in order to obtain information regarding aspects of their experience interacting with the review process and resources offered by the Rowan University Office of Research Compliance.

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Appendix A

IRB Approval Documentation

** This is an auto-generated email. Please do not reply to this email message.
The originating e-mail account is not monitored.
If you have questions, please contact your local IRB office **

DHHS Federal Wide Assurance Identifier: FWA00007111
IRB Chair Person: Harriet Hartman
IRB Director: Sreekant Murthy
Effective Date:

eIRB Notice of Approval

STUDY PROFILE

Study ID: Pro2018000111
Title: IRB Quality: A Study of the Rowan University IRB

Principal Investigator:	Tyrone McCombs	**Study Coordinator:**	
Co-Investigator(s):	Andrew Gerber	**Other Study Staff:**	There are no items to display
Sponsor:	Department Funded	**Approval Cycle:**	Not Applicable
Risk Determination:	Minimal Risk	**Device Determination:**	Not Applicable
Review Type:	Exempt	**Exempt Category:**	2 i

CURRENT SUBMISSION STATUS

Submission Type:	Research Protocol/Study	**Submission Status:**	Approved
Approval Date:	2/7/2019	**Expiration Date:**	
Continuation Review Required:	Progress Report		

Pregnancy Code:	No Pregnant Women as Subjects	**Pediatric Code:**	No Children As Subjects	**Prisoner Code:**	No Prisoners As Subjects

Protocol:	Protocol_Pro2018000111 Alternate Consent_Pro2018000111 Recruitment Email_Pro2018000111 IRB-RAT Instrument	**Consent:**	There are no items to display	**Recruitment Materials:**	There are no items to display

*** Study Performance Sites:**

Glassboro Campus 201 Mullica Hill Road Glassboro, NJ 08028

There are no items to display

Appendix B

Recruitment Email

From: **Gerber, Andrew** gerbera2@students.rowan.edu
Subject: IRB Study Participation: Pro2018000111
Date: February 8, 2019 at 2:53 PM
To: undisclosed-recipients:;
Bcc:

AG

Hello,

My name is Andrew Gerber, and I am a graduate student in the M.A. in Higher Education program at Rowan University. I am conducting a study to learn more about how Rowan University IRB members and administrators evaluate the overall performance of their IRB. This work may provide a better understanding of where the IRB currently excels, and where its performance could be brought in closer alignment with the values of its members.

This IRB-approved study (study #Pro2018000111) consists of a survey, which may take approximately 15 minutes to complete. The survey is anonymous, with no identifying link retained in the data provided. Your participation is entirely voluntary.

If you are interested in contributing to this study, and would like to learn more, please follow the link to the survey below:

https://rowan.co1.qualtrics.com/jfe/form/SV_3CSzihHnOmWO8y9

If you have any further questions, please feel free to contact me by replying to this email.

Thank you,

Andrew Gerber