# Barriers and Bridges: Dual Perspectives on IRB Application Quality

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## Executive Summary

### Definitions

Below is a collective glossary of key terms used throughout this paper.


### Background & Significance

Research conducted on human subjects had led to scientific, medical, and social advances that have shaped the modern world. Given the dynamism and influence of the research enterprise, human subjects research demands oversight and regulation. In the United States, all human subjects research must be reviewed and approved by an Institutional Review Board (IRB), whose charge is to protect the rights and welfare of the human subjects participating in research. The IRB fulfills this obligation by performing review in accordance with federal regulations and established ethical principles.

Beyond the mandate of protecting human subjects, an IRB has a responsibility to educate the research community it serves on how to navigate IRB review. Federal regulations establish the required criteria for approval for the conduct of human subjects research (45CFR§46.111). Without satisfying this criteria, the IRB cannot approve an application for a proposed human research study.

### Literature Review, In Brief

Throughout the published literature, calls have been made for a greater understanding of quality within the field of human subjects research (Abbott & Grady, 2011; Lynch, et al., 2019; McDonald & Cox, 2009; Nicholls, et al., 2015; Resnik, 2021; Scherzinger & Bobbert, 2017; Taylor, 2007; Tsan, 2019; Vawter, et al., 2004). IRB review quality has been the primary focus of such requests however, the quality of IRB applications is equally significant and requires in-depth inquiry. Inattention to the IRB application itself is consequential because the application precedes IRB review, and perceptions of quality between the two may be interrelated and interdependent.

In addition to calls for examining quality, the research community has also requested increased clarity on IRB decision-making. A central criticism of IRBs is their lack of transparency and failure to clearly explain why or how their requests correspond to a specific regulation or ethical position. Given the IRB's power and authority, researchers subject to their directives find the ambiguity of IRB review unacceptable, and rightly so. This tension can strain relationships and cause mistrust between researchers and the IRB, potentially compromising research compliance as a result.

Without a clearer appreciation for the roles that both quality and clarity play on the IRB application review process, regulatory burden and insufficient regulatory knowledge are commonly misattributed as the reason an IRB application lacks quality. The literature insists that if researchers simply had greater regulatory knowledge, their IRB applications would be perfect. As a result, IRBs have principally focused their educational and support efforts on regulatory training.

**Problem of Practice**

Contrary to the established literature, researchers do not need to be experts in the regulations to achieve a quality IRB application for two reasons. The first is that, despite the availability of federal criteria, research regulations do not provide researchers with a straightforward roadmap of how to prepare a complete, approval-ready IRB application. The regulations also do not prescribe how research proposals are submitted to the IRB, nor do they codify the components of a standard IRB application or describe what a "quality" application looks like.

The second reason researchers do not need to be experts in the regulations to achieve a quality IRB application is because a regulatory-forward community of practice is a reasonable goal for IRB professionals but not for researchers. For IRB staff, ensuring compliance with federal regulations and ethical principles are straightforward components of their day-to-day work. For researchers, however, these nuances are not so apparent or instinctive, and may not even be necessary. While the regulations are essential to provide guardrails to researchers, solely focusing on researchers' regulatory literacy is a pedagogical misstep. As this project illustrates, it is the IRB's responsibility to "translate" the regulations into plain and actionable language throughout their application materials, support resources, education, and training. If done skillfully, researchers have the opportunity to produce a quality application that meets all of the regulatory criteria for approval without referencing the regulations at all.

Operationalization of a "quality" IRB application is urgently needed to prepare researchers and IRB professionals alike for a successful review experience. Characterizing the perspectives of both IRB professionals and researchers can uncover perceived barriers and bridges to achieving quality. From this multidimensional understanding, conclusions can be drawn that will help academic and scientific communities to: 1) identify their perceptions and characterizations of quality, 2) establish expectations of quality within IRB applications, and 3) deploy resources to researchers that will facilitate quality IRB application preparation.

**Conceptual Framework**

A reimagined version of Experiential Education and Transformational Learning theories presents a constructivist approach to, and conceptual framework for, creating novel learning environments for researchers. In brief, this combined framework offers two components: 1) The need for educators to interrogate the pedagogical status quo of didactic teaching, and 2) a co-

constructed approach to learning that situates interaction, collaboration, mutual goals, and sensemaking at its center.

Experiential education theory emphasizes learning that extends beyond classroom walls and expands into the real world. Conducting human subjects research is an activity entirely situated in the real world with tangible risks and benefits – including life and death. Involving researchers in creating their own learning environments, co-constructing training that satisfies their needs and wants in partnership with the IRB, provides opportunities to find both support and practical, real-world application of research regulations and ethical research principles.

**Partner Organization**

To conduct a thorough inquiry, I selected a partner organization that has a large, multidisciplinary research community. Mass General Brigham (MGB) is a Boston-based non-profit hospital network that was founded in 1994. It is a leading national integrated health care system that has 14 affiliated member institutions, over 100 accredited physician residency and fellowship programs, and over 2,000 trainees preparing for the field of medicine. As part of MGB's research administration shared services model, the IRB supports the research activities at all 14 member hospitals.

Based on my experience in the field, MGB is an ideal organization to investigate IRB application quality due to their sizable research portfolio, multiple affiliate institutions, and researchers of varying levels of experience. I have worked within academic Institutional Review Boards for over 15 years, reviewing human subjects research for ethical conduct and compliance with federal regulations, state laws, and institutional policies. My areas of expertise are the protection of the rights and welfare of participants involved in medical and social-behavioral research, and providing consultation and research support to investigators.

**Study Design, Methods, & Data Analysis**

This study used a qualitative, descriptive, cross-sectional design to gather individual perspectives on the concept of a "quality" IRB application. Individual interviews provided a method of inquiry to characterize perceptions belonging to two participant cohorts: Group 1) MGB IRB Professionals and Group 2) MGB Researchers.

Interviews were conducted with participants until thematic saturation was achieved. This was accomplished after interviewing 9 MGB IRB Professionals and 11 MGB Researchers. During data collection, I used analytic memos and cumulative induction to assemble each cohort's data and to develop the coding structure.

Qualitative data coding and analysis were performed using the methodology of Miles, Huberman, & Saldaña (2014); coding interview transcripts first with broad 1st level codes, expanding their meaning with a specified 2nd level code, and generating 3rd level codes of even greater detail. Each step in the coding-generating process was performed using MAXQDA software. All data analysis was manual and iterative; I did not use any automation to assist with this activity. Analysis concluded when I had developed a network of understanding about my topic through interpretation of participant data, as well as patterns, themes, and concepts that emerged from coding.

**Project Questions, Findings, & Recommendations**

Analysis of interview data through qualitative coding and thematic examination led to eight core findings and seven recommendations. Through these conclusions, I have innovated a

precise and actionable roadmap for preparing quality IRB applications at MGB.

| Project Questions | Findings | Recommendations |
|---|---|---|
| 1. What are the characteristics and other determinants of a high-quality human subjects research IRB application? | 1. Characterization of a High Quality IRB Application<br>2. Characterization of a Poor Quality IRB Application<br>3. Four Determinants of Impact<br>4. Biggest Determinant of a High Quality IRB Application<br>5. The Barriers and Bridges to IRB Application Quality | 1. Establish an Internal Evaluation Process<br>2. Support a Start-to-Finish Framework<br>3. Enhance the User-Friendliness of the IRB Experience |
| 2. How do IRB Professionals and Researchers overlap and differ in their characterization of quality? | 6. Three Focal Points of Overlapping and Contrasting Perceptions of Quality at MGB | *(intentionally blank)* |
| 3. What resources are needed to assist researchers in producing high-quality human subjects research IRB applications? | 7. Unsuccessful Support Strategies in Achieving a Quality IRB Application<br>8. Successful Support Strategies in Achieving a Quality IRB Application | 4. Introduce Point of Performance Training<br>5. Appoint a Dedicated IRB Point Person<br>6. Supply "The Why"<br>7. Create an Exemplar Library |

*Table 1 – Summary of Project Questions, Findings, and Recommendations*

**Using Bridges to Overcome Barriers**

Overwhelmingly, MGB Researchers and IRB Professionals agree that project-specific consultation and human help are the most successful support strategies when it comes to producing a quality IRB application (Finding 8). Based on these preferences, there is strong evidence to shift away from general regulatory training and towards Point of Performance training instead (Recommendation 4). Researchers are actively and practically ready to receive IRB training at the point of performance (i.e. when they are ready to submit their IRB application). It is at this inflection point that they are motivated to successfully navigate the application process and submit a quality application.

The IRB application process is an experiential one. Much like learning to ride a bike – you can't acquire that skill by reading about it in a book; you need to be on the bike and ready to ride. Experiential and transformative education frameworks hold the most promise in solving this problem of practice because they firmly root learning in "the dynamic present" – in other words, at the point of performance. By co-constructing the learning environment in real-time, at the point of performance, IRB professionals and researchers engage in modeling and mastery within the researcher's own application and produce lasting lessons that can be repeated in future applications.

# BARRIERS AND BRIDGES: DUAL PERSPECTIVES ON IRB APPLICATION QUALITY

## Introduction

Throughout the published literature, calls have been made for a greater understanding of quality within the field of human subjects research (Abbott & Grady, 2011; Lynch, et al., 2019; McDonald & Cox, 2009; Nicholls, et al., 2015; Resnik, 2021; Scherzinger & Bobbert, 2017; Taylor, 2007; Tsan, 2019; Vawter, et al., 2004). IRB review quality has been the primary focus of such requests however, the quality of IRB applications is equally significant and requires in-depth inquiry. Inattention to the IRB application itself is consequential because the application precedes IRB review, and perceptions of quality between the two may be interrelated and interdependent.

A high-quality IRB application can convey the skills and capacities of its authors. It can implicitly communicate core competencies about the research team to the IRB, including their regulatory literacy, experience conducting research, ability to communicate complex research concepts and methods, and capacities impacting research compliance. On the other hand, a poor quality IRB application may signal deficits, training needs, inattention to detail, inexperience, lack of resources, inappropriate workload delegation, and possible future noncompliance.

Ultimately, whether high or low, the quality of the IRB application will convey to the IRB how the research will be conducted. Because the IRB's primary mandate is to protect the rights and welfare of human subjects, the measure of quality is bound by how completely the researcher has described all research procedures start to finish. Without a full accounting, the IRB cannot assess the regulatory, ethical, scientific, and administrative requirements of a proposed human subjects research study. To this end, the IRB is capable of, responsible for, and well-positioned to strengthen the research-practice nexus, starting with IRB application quality.

The literature reviewed as part of this study examines the background and significance of federal research regulations, regulatory burdens, researchers' regulatory literacy, and research administration educational models. The roles of both research administrators and the IRB are critically important to the IRB application process – and will be described operationally and relationally. Further, research administrators' collective responsibilities in reducing burden on researchers, providing regulatory support, and promoting research compliance will be articulated.

A reimagined version of Experiential Education and Transformational Learning theories will present a constructivist approach to, and conceptual framework for, creating novel learning environments for researchers. This, in combination with theoretical, practical, and empirical evidence from the literature and data collected from the partner organization, will inform the design and development of quality-forward pedagogical paradigm for researchers.

## Organizational Context

Mass General Brigham (MGB) is a Boston-based non-profit hospital network revolutionizing patient care, teaching, and research. MGB was founded in 1994 and is a leading national integrated health care system, including Brigham and Women's Hospital and Massachusetts General Hospital, two of the nation's most prestigious teaching institutions. MGB

has 5 licensed and 14 affiliated member institutions and over 100 accredited physician residency and fellowship programs and over 2,000 trainees preparing for the field of medicine.

MGB supports the research activities at all of their 14 member hospitals. In this shared services model, the research support offices facilitate the administrative, financial, and regulatory requirements of research and sponsored projects received by MGB member institutions (see Appendix A for the full list of MGB members/Covered Entities).

The MGB Human Research Protection Program (HRPP) is an integrated program with overall responsibility for protecting the rights and welfare of human subjects participating in MGB research. The MGB HRPP is responsible for reviewing and overseeing research activities involving human subjects as conducted by all Covered Entities under the MGB HRPP, and has jurisdiction over all research conducted at these sites. A core mission of the MGB HRPP, and MGB in general, is to advance care through excellence in biomedical research. Consistent with this core mission, the HRPP's mission is to ensure that MGB and its hospitals protect human subjects participating in research in accordance with regulatory requirements and ethical guidelines. The HRPP fosters a culture of compliance with the highest standards for human subject protection among the institutions, their investigators, and all members of the research community. The MGB HRPP is currently accredited by the Association for Accreditation of Human Research Protection Programs (AAHRPP) and has been since December 2004.

Governance of the MGB HRPP is coordinated between MGB and the HRPP Covered Entities. MGB is the overall corporate parent of the HRPP Covered Entities as well as several other health care provider entities. MGB has a Board of Directors, which generally manages and directs the overall health care system. However, the HRPP Covered Entities are each legally separate corporate entities. As such, they each have their own Boards which carry out core responsibilities with respect to the hospitals. The HRPP Covered Entities are each distinct recipients of external funding and have their own Federalwide Assurances (FWAs) with the U.S. federal government signed by their own Institutional Officials (IOs), who are legally authorized to represent each institution.

The Institutional Review Boards of MGB are known collectively as the MGB Institutional Review Boards (IRB). The IRB provides oversight for MGB entities identified in Appendix A, as well as entities designating MGB as the IRB of Record for specified research. The IRB provides review and continuing oversight of human subjects research to protect the rights and welfare of the research participants. The IRB is committed to following the letter and spirit of the human subject protection regulations, guidance, MGB policies, and accreditation standards to ensure the integrity of the IRB decision-making process. The IRB operates in full compliance with all applicable federal, state, and local laws and regulations, as well as site-specific requirements and policies. The responsibility for the protection of human subjects is shared by both the institutions and the investigators conducting the research (MGB, 2021).

## Problem of Practice

Despite the availability of federal criteria, research regulations do not provide researchers with a straightforward roadmap of how to prepare a high quality IRB application. The regulations also do not prescribe how research proposals are submitted to the IRB, nor do they codify the components of a standard IRB application or describe what a "quality" application looks like. As a result, preparing an approval-ready IRB application is a challenge. There are differing perspectives among which approach predicts the strongest IRB application: regulatory

literacy, subject matter expertise, a fastidious application – or some combination thereof. This study challenges and critiques conventional understandings of this problem of practice.

In addition, a practical and efficacious roadmap to help researchers produce high quality IRB applications is needed. Without such a roadmap, the challenges represented in Figure 1 face IRBs, researchers, and their institutions. These downstream impacts can harm participants, impede compliance, and hinder critical research activities.

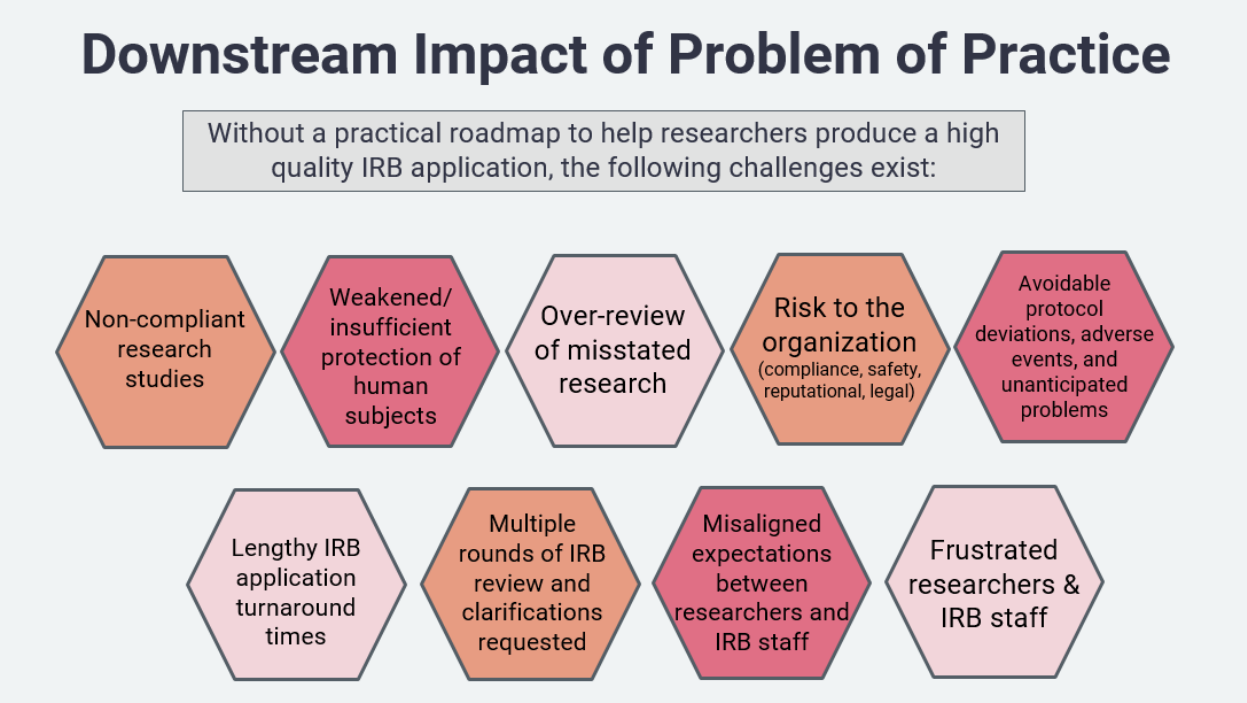


*Figure 1 - Downstream Impact of Problem of Practice*

Characterizing the perspectives of both IRB professionals and researchers can uncover perceived barriers and bridges to achieving quality. From this multidimensional understanding, conclusions can be drawn that will help academic and scientific communities to: 1) identify their perceptions and characterizations of quality, 2) establish expectations of quality within IRB applications, and 3) deploy resources to researchers that will facilitate quality IRB application preparation.

## Literature Review

The extant literature on regulatory burden is abundant, and numerous studies have been conducted to address the consequences on researchers and their institutions. However, there are gaps in the literature connecting the financial, compliance, psychological, and learning costs of burden to the entire cast of characters involved in institutional research administration and management. To thoroughly explore this operationally diffuse process, the literature reviewed here examines the federal research regulations, regulatory burdens, researchers' regulatory literacy, and research administration educational models. The roles of both research administrators and the IRB within these functional areas are described (operationally and relationally), and their collective responsibilities in reducing burden on researchers, providing support, and promoting research compliance are articulated.

Regulatory burden and regulatory knowledge is commonly misattributed as the reason an IRB application lacks quality. As the literature insists, if researchers simply had stronger regulatory knowledge/backgrounds, their applications would be perfect. With this in mind as the problem of practice, the human research protections field has focused its educational and support efforts on regulatory training. Using the regulations as a scapegoat in this way has historically obfuscated the path to IRB application quality. As this project demonstrates, a regulatory-forward community of practice makes sense for IRB Professionals but does not for Researchers.

In contrast, the regulations are necessary to provide guardrails to the research enterprise. Ultimately, the IRB must ensure all human subjects research meets a specific set of regulatory criteria for approval before approving a project. Contrary to the established literature, researchers do not need to be experts in that criteria to achieve a quality IRB application. As this project illustrates, it is the IRB's responsibility to "translate" the regulations in plain language throughout their application materials, support resources, education, and training. If done deftly, researchers have the opportunity to produce a quality application that meets all of the regulatory criteria for approval without referencing the regulations at all.

**Federal Research Regulations**

The United States Code of Federal Regulations (CFR) is a set of laws whose purpose is to provide structural and legal consistency and oversight within their respective federal agencies. There are 50 titles within the CFR that represent broad areas subject to regulation by the federal government - domestic security, federal elections, agriculture, education, and public welfare, to name a few.

The federal code pertaining to human subjects research falls under the purview of the U.S. Department of Health & Human Services (HHS). In 1991, the "Common Rule" regulations (45CFR§46) were published and adopted by 16 U.S. federal agencies. The Food & Drug Administration (FDA) is not a Common Rule agency because its regulatory jurisdiction differs; 21CFR§56 regulations pertain to clinical investigations of drugs, biological products, and medical devices; however, the FDA is required to harmonize with the Common Rule whenever permitted by law. As it is federally mandated, IRBs may only approve human subjects research in accordance with these regulations.

The goal of federal research regulations is to provide direction on conducting compliant, ethical, valid, reliable scientific research involving human subjects. Given the impact of both biomedical and social-behavioral human subjects research, regulatory oversight and public policy implementation under Congress provide normative standards for researchers. However, as this oversight is implemented in practice, such regulations can pose substantial burdens on researchers and their work.

**Regulatory Burdens of Research**

Nearly all researchers agree on the deliberate and objective need for the protection of human subjects and clear rules for consistency, safety, transparency, and integrity in the conduct of research involving humans (National Science Board, 2014; Association of American Medical Colleges, 2016). However, the regulations themselves are complex, overly technical/legalistic, can be seemingly inconsistent, include domain-specific terms unfamiliar to novices, and are not organized in an intuitive way for the reader (Hale et al., 2011; Association of American Medical Colleges, 2016; Law et al., 2014).

Deciphering the regulations is problematic for researchers because it is excessively time-consuming, which can impede compliance and hinder the public's understanding of government oversight (Law, Lau, Kerrigan, & Ekstrom, 2014). As McLaughlin & Holmes (2015) point out, the word count of the entire CFR is 103,079,294 and would take 5,727 hours to read. Given both the density and volume, it is unsurprising that the current state of the regulations has caused regulatory overload and resulted in layers of additional work for researchers (National Science Board, 2014). Ensuring regulatory compliance, then, becomes costly, both in terms of time and resources, neither of which researchers typically have the luxury of.

With regulatory complexity comes a myriad of resultant requirements necessary to ensure compliance. In their 2016 report addressed directly to the President of the United States, the Association of American Medical Colleges (2016) bluntly stated that "the unintended cumulative effect of federal regulations places significant stress on institutions and individual researchers that can impede research productivity and innovation" (p. 21).

Government agencies have received unambiguous feedback that regulatory burden is impeding innovation and research productivity and reducing the return on investment of federal funds. For example, in 2012, the Federal Demonstration Partnership survey found that federally funded researchers spent, on average, 42% of their time performing administrative tasks - including ensuring compliance with federal regulations - instead of conducting research (Association of American Medical Colleges, 2016; Leshner, 2008). Further, a 1999 report by the National Institutes of Health (NIH) identified that researchers are subject to roughly 60 sets of research-related regulations and, upon closer inspection, found that the cumulative impact of just five of these regulations on researchers was "interrelated and…synergistic in a negative sense" (Mahoney, 1999, p. 1). A regulatory landscape that is cumbersome and onerous to navigate precipitates non-compliance and demands intervention.

**Addressing Researchers' Regulatory Literacy**

The extant literature describes why researchers lack the capacity, resources, attention, and desire to retain information about research regulations and IRB processes and policies. Overall, a researcher's primary goal is to conduct their research. However, secondary and tertiary administrative requirements can prohibit a researcher from focusing solely on this goal. For example, administrative duties, grant management, hiring study personnel, purchasing equipment and supplies, submitting applications/paperwork, securing intellectual property protections, negotiating and obtaining agreements/contracts, and so on, shift valuable time and attention away from conducting one's research activities (Wimsatt et al., 2009; Mullen et al., 2008). Further, Wimsatt et al. (2009) point out that "heightened demands for accountability, increased competition for research grants, expanded demands on faculty time…are among the challenges that make achieving institutions research missions increasingly difficult" (p. 72). Mullen, Murthy, & Teague (2008) found in their survey of over 6,000 faculty members that 95% could spend more time on active research if they had more administrative assistance. This finding is consistent with the observable pressure and demands on faculty's time - between clinical duties, committee work, teaching, mentoring, producing scholarly work, and their research, to name a few.

Within the literature, and anecdotally, there exist at least six root causes of researchers' regulatory knowledge gaps (AAMC, 2016; Bozeman & Youtie, 2020; Decker et al., 2007; National Science Board, 2014; Nichols & Wynes, 2018; Silberman & Kahn, 2011; Wimsatt et al., 2009). First, researchers lack capacity and rely on IRB staff to inform them about specific

issues or direct their attention when needed. Second, knowledge gaps are just that: disparities in experience or understanding. Research administrators cannot expect researchers to have the same depth of knowledge on the regulations or internal standard operating procedures as they have. Third, researchers may not know where to seek education or assistance, even when they recognize a knowledge gap. This could create a perception of lack of support, even though multitudinous resources exist. Fourth, there may be a disconnect between the frequency of regulatory change that is perceived by researchers. To the research community, policies, procedures, rules, and regulations change too frequently and knowledge retention suffers as a result. Fifth, research-related administrative tasks are frequently delegated by the Principal Investigator to a research assistant or research coordinator. Frequent turnover in such roles can create barriers to retaining legacy knowledge. Finally, some seasoned researchers do understand and follow IRB policies and procedures with near-perfect accuracy, however there are specific, nuanced, complex, highly technical areas outside of their existing IRB knowledgebase (e.g., reliance agreements, the EU General Data Protection Regulation).

Given the fact that top-down regulatory burden reform from the federal government is unlikely to occur, it is prudent for research institutions to address concerns of burden by providing regulatory support and promoting compliance in innovative new ways. Geller et al. (2010) authored one of the first publications critiquing regulatory-only education for researchers. The authors report that training researchers on how to conduct ethical research may be a more practical focal point of their learning, especially if regulatory issues can be handled by the IRB.

> "The abundance of rules can distract conscientious investigators from focusing on the ethical underpinnings of the regulations…[Researchers understand that] attention focused on compliance does not mean that the ethical underpinnings of the regulations are less important…Although compliance is important for both investigators and the IRB, there is confusion about the relative attention that each party should pay to it" (p. 1300).

**Approaches to Research-Related Educational Models**

Typically, when researchers have knowledge gaps, the solution is to provide education and training. One method to disseminate educational information among researchers is in cross-disciplinary publications that simultaneously address field-wide research concerns while navigating the IRB process. For example, journals on public health surveillance, anthropology, special education, pharmacy science, nursing, LGBTQ+ research, to name just a few, have published articles on the history and function of IRBs, levels of IRB review, as well as how to work with IRBs (Baer et al., 2014; Gordon, 2003; Murphy & Verden, 2011; Phillips et al., 2017; Rutherford-Hemming et al., 2012; Sims, 2008; Tufford et al., 2012). It is reasonable to utilize academic journals in this way; it is logically where academics and scholars seek information. However, while readily accessible, these resources are problematic because they are static and typically become outdated quickly. Further, they do not address institution-specific IRB policy requirements, and they are generally overbroad and unable to answer questions relevant to a particular research project or investigator's concerns.

Hale et al. (2011) proposed that, in the absence of eliminating superfluous regulations, which is unlikely, the next best thing is to increase the accessibility of the regulations. However, in a program analysis conducted by DeMoss et al. (2018), research administrators discovered that their educational initiatives actually transferred administrative burden back on to researchers because training sessions were much too detailed and researchers do not have the time nor attention to retain such high levels of specificity. DeMoss et al.'s discovery allowed their team to

shift their priority from expecting full content mastery to a more realistic takeaway for their audience: they know regulatory compliance is required and whom to contact with questions.

Volumes of research have been published on how learners identify and close knowledge gaps. A study conducted by Eva & Regehr (2011) on students' professional self-regulation found that when an individual receives feedback on their knowledge gaps, their natural response was to try and improve. Even more encouraging was that this response was not based on any reward, simply the personal satisfaction of learning something new or correcting a prior misunderstanding. The research of Huang & Hung (2018) and Loibl et al. (2017) had analogous findings with respect to how learners identify knowledge gaps and how this motivates learning. Both studies concluded with findings that show that when students are faced with new problems, they first activate their prior knowledge. Facing an authentic problem promotes identification of a knowledge gap because it is a lived experience (i.e., real world experience matters). This identification process is essential because it then primes the individual to either learn something new or modify their existing understanding. Further, when later provided with instruction in an area where a known knowledge gap exists, individuals paid more attention to that content because they recognized it as knowledge they knew they lacked. These findings suggest a promising set of tools for IRB staff to use: give researchers feedback on knowledge gaps, evaluate how researchers activate prior knowledge, recognize researchers' motivation to learn, and provide instruction that will precisely target the gap.

The literature suggests an intuitive approach to developing an education efforts focused on research competencies. Education should be simple and streamlined, information should be distributed in a timely fashion, materials should be presented in formats and venues that are useful and user-friendly, infrastructure should be intentional and organized, redundancies should be reduced, and efforts should be focused on direct users (Wimsatt et al., 2009; Mullen, Murthy, & Teague, 2008; Rutherford & Langley, 2007). Other useful considerations included being mindful of the discretionary time researchers have/want to spend on such education, the possibility of incentivizing researchers to participate, and seeking advocacy from other researchers, or "superusers," who can help promote the IRB's support services. Finally, Rutherford and Langley (2007) observed that keeping the research community frequently informed of such initiatives is critical; research administrators may underestimate how much researchers actually know about services and support available to them. Early career researchers typically have a novice understanding of IRB policies and procedures; however, they have numerous institutional touch points to gain education and training. On the other hand, longstanding, established researchers may engage less often with the IRB because they have prior experience and exposure to the process.

## The Roles of Research Administrators & IRB Professionals

### *Research Administrators*

The research enterprise is an intricate environment with numerous interrelated and overlapping functions, priorities, and complexities. Most research-supporting organizations include centralized research administration offices designed simultaneously to support and implement innovative and transformational research, generate and secure research funding, establish research collaborations and partnerships (both domestically and internationally), and train the next generation of research scholars (Figure 2).


*Figure 2 - Research Administration Compliance Areas (Adapted from U. of Texas)*

Staff employed within research administration offices are responsible for ensuring regulatory compliance, administering funding, establishing research oversight policies, managing conflicts of interest, responding to research misconduct, and promoting the responsible conduct of research. As such, research administrators must have an extensive body of specialized expertise required to meet the demands of the field (Wagonhurst, 2002; Atkinson et al., 2007).

A critical component of research administration is the need to navigate relationships and interactions with an extremely broad client base within the research community (faculty, scientists, senior leadership, students, and others), and do so while being mindful of social roles and professional culture within the institution (Greenwood, 1957; Atkinson et al., 2007). Atkinson et al. (2007) quoting Hensley (1986) affirmed that "research support personnel are essential…to the achievement of the specific missions of postsecondary institutions…yet this vital group's value to science is largely unrecognized [in the literature]" (p. 1).

Due to this inextricable relationship, the interaction between research administrators and the research community must be collaborative, cooperative, and complimentary. Wimsatt et al. (2009) and Ross (1990) agree that "developing and maintaining effective partnerships between faculty and research administrators is a critical issue if both are to be in a position to do their best work" (p. 74) and that these relationships are "a key variable in determining the success of an organizations research endeavor" (p. 21).

One key challenge for research administrators is to manage the differing priorities between their responsibilities and the research community's interests. Ross (1990) identified that

> "administrators are often the messengers, monitors, and enforcers of regulations; thus, they are the most convenient targets for the ire that researchers may…direct at the regulations and regulators. The challenge to those who implement regulations at the institutional level is to ensure compliance in a way that does not unduly interfere with the…research by the investigator. The task is to serve the needs of the investigators by creating an institutional environment that will help the investigator meet [their] regulatory obligations" (pp. 19-20).

Serving the needs of the researchers is a paramount and required part of research administration work. Research administration teams devote countless hours to education, training, guidance, and support services. However, one pressing concern for research administrators, specifically within the IRB, is to ensure that those efforts are fruitful and sustainable. It is inefficient for research administrators to dedicate precious time and resources to outmoded pedagogical approaches that will not yield high quality IRB applications.

### *IRB Professionals*

In the book, *Regulating Human Research*, Babb (2020) describes the seemingly overnight professionalization of IRB work. It was an adaptive response to the rapid expansion of the research enterprise in the 1990s, and the concurrent need for professionals with regulatory and ethical expertise to review that research. Volunteer faculty and clinicians who loosely applied the regulations and produced sparse documentation were no longer adequate in these roles. Organizations began investing heavily in full-time IRB staff with advanced credentials. Growth in the field promised fulfilling careers ahead:

> "There was a growing sense that mastering the regulations was too important to leave to the amateurs…Whereas filing paperwork could be carried out by clerical staff, correctly interpreting what documents regulators would want to see in an audit required considerably more skill. Not only were the regulations complex and ambiguous, but they were fragmented and inconsistent…As regulatory agencies issued new guidance…it created yet another level of esoteric complexity in need of expert interpretation" (Babb, 2020, pp. 36-37).

During this time, IRB professionals emerged as skilled regulatory and compliance experts who enhanced IRB operations and audit trails. The introduction of the Certified IRB Professional (CIP) credential elevated and validated the higher-level competencies required of IRB staff. The establishment of the field's professional organization, Public Responsibility in Medicine and Research (PRIM&R), created a community of practice and legitimized the occupational identity of IRB professionals across the U.S.

## The Role of the IRB: IRB Application Process and Review

A central criticism of IRBs is their lack of transparency and failure to clearly explain why or how their requests correspond to a specific regulation or ethical position. Researchers may come to see these requests as a superfluous fishing expedition, or worse - research administration writ large as a burden and a barrier. IRBs have a reputation of hiding behind a veil of anonymity, not providing a rationale or justification for their decisions, and seeking arbitrary revisions that fundamentally change the scope of the research (Klitzman, 2012; Lynch, 2018; Resnik, 2021).

Given the IRB's power and authority, researchers subject to their scrutiny and directives find the opacity of IRB review unacceptable, and rightly so. The tension caused can strain

relationships and cause mistrust between researchers and the IRB, and potentially compromise research compliance as a result.

To IRB staff, ensuring compliance with federal regulations and ethical principles are straightforward components of their day-to-day work. However, to researchers, these nuances are not so apparent and may not be instinctive. This disconnect is the source of most tension within the IRB application and review process; IRB staff see the regulations as instructive, researchers see the regulations as unclear and convoluted. Much of the established literature calling for clearer standards of evidence for IRB quality and decision-making make little or no mention of the caliber of the IRB application submitted by the researcher: "A standard of evidence for an IRB would be rule or guideline concerning the type or amount of evidence that is needed to make an approval decision" (Resnik, 2021, pp. 2-3). To establish measurable review metrics, IRB's first need to operationalize what is meant by "quality" or "good" IRB applications.

## The Concept of "Quality"

### *Ground-laying Research on Quality*

Much of the established literature on quality is rooted in industry: consumer-focused businesses, goods-production, service sectors, consumer markets, economic modeling, manufacturing, agriculture, telephone/technology networks, and global marketplaces. Quality sub-disciplines began to emerge throughout the 1950s-1970s, including W. Edward Deming's management-focus on statistical process control; Joseph Juran's seminal work, the *Quality Control Handbook*; Armand Feigenbaum's influential quality management book, *Total Quality Control*; and Philip Crosby's "zero defects" approach to quality, which laid the groundwork for Six Sigma (Avci, 2017; Chandrupatla, 2009; Reeves & Bednar, 1994).

Empirical research on quality has focused principally on the healthcare field; where healthcare communities, providers, insurers, and federal assistance programs have sought to use clinical measures, including emergency care, hospitalizations, and re-admission rates, to determine the quality of patient care (Codman, 2013; Donabedian, 1985; Donabedian, 1988). In addition to the medical field, the quality of higher education is emergent in the empirical literature; however, the groundwork is relatively new (beginning in the 1970s) and is often studied in combination with the cost of education, institutional rankings, attrition and retention, and campus demography. In other words, defining quality in academia is fragmented among many competing interests including, but not limited to, teaching and curriculum development, learning and academic mastery, resource allocation, job/workforce preparation, and progressing research, discovery, and innovation (Green, 1994; Harvey & Green, 1993).

### *Initial Attempts to Define Quality*

One commonality found throughout the body of prior literature is the initial attempt to utilize the broadest definition of quality available - "degree of excellence" (Merriam-Webster Dictionary, 2021) - and the swift rejection of this definition as too abstract, immeasurable, and impractical. Further, where the concept of quality is dependent on human contact and interpersonal interactions, there is even more complexity where no monolithic definition seems to fit.

Unanimously, the published literature agrees that the concept of quality is domain-specific, stakeholder-relative, and contextually bound. From service encounters, to customer satisfaction, to precision medicine, "quality" is unique to the beholder based on their individual

goals, attitudes, needs, interests, expectations, and standards (Avci, 2017; Donabedian, 1988; Harvey & Green, 1993; Reeves, C.A. & Bednar, 1994). Reeves & Bednar (1994) aptly state:

> "A search for the definition of quality has yielded inconsistent results. Quality has been variously defined as value (Abbott, 1955: Feigenbaum, 1951), conformance to specifications (Gilmore, 1974; Levitt, 1972), conformance to requirements (Crosby, 1979), fitness for use (Juran, 1974 1988), loss avoidance (Taguchi, cited in Ross, 1989), and meeting and/or exceeding customers' expectations (Gronroos, 1983; Parasuraman, Zeithaml, & Berry, 1985). Regardless of the time period or context in which quality is examined, the concept has had multiple and often muddled definitions and has been used to describe a wide variety of phenomena" (p.419).

An interdisciplinary query of the literature on quality confirms this position remains true.

### *Quality Frameworks Analogous to Human Subjects Research*

The business, healthcare, and education sectors' definitions of quality are useful benchmarks but are not a precise enough analog for the quality of human subjects research applications, nor the work of IRBs. There are three papers in the available literature that are useful approximations of models on quality relevant to the questions posed in this paper. They are presented here in order of applicability, from broadest to narrowest.

**Quality in Bioethics Education.** The first is Avci's (2017) work which defines a quality framework for bioethics education by "elaborate[ing on] the concept of quality, focus[ing] on its understanding in education and explor[ing] a definition of quality in bioethics education" (p. 201). Avci's paper on defining quality in ethics education offers four transferrable ideas to the concept of IRB application quality presented in this paper.

First, Avci's work also draws on other disciplines studying quality, and corroborates the origins on quality in the extant literature summarized above. Second, it is foundationally grounded in a comparable context to my work on IRB application quality; it also intersects an ethics-focused, education-based domain of inquiry. Third, Avci's work establishes that defining quality in bioethics education should include clear goals and how those goals will be satisfied. Concretely, "quality in bioethics education is an ongoing transformative process to: increase ethical knowledge; improve ethical skills to strengthen ethical sensitivity, awareness and judgment; develop ethical behavior; and promote cultural competence" (Avci, 2017, p. 211). This goal formation provides both a pathway to achievement and a framework for measurement for other bioethics-centric education efforts, similar to this project. And fourth, Avci reaches a definition of quality described as "conformance to goals," which is simultaneously useful in the regulated world of IRBs, since we are professionals specializing in compliance, and because fulfillment of these goals serves the learner's larger purpose of progressively building a body of ethics competencies.

**Practical Guidance to the IRB Review Process.** The second instructive publication is Pech et al.'s (2007) paper providing practical guidance on navigating the IRB application process. The paper articulates "the central features of IRB review and required determinations, along with practical advice for preparing IRB applications and associated study materials" (p. 618). The work of Pech et al. (2007) is as close to a guide on how to produce a quality IRB application that exists in the literature, without that being the author's stated intent.

Pech et al.'s paper builds a preliminary roadmap for researchers preparing an IRB application by individually itemizing each regulatory criterion for approval (found in 45 CFR 46) paired with common IRB clarifying questions. The goal is to equip researchers with prompts to

anticipate questions their IRB may ask of them. Certainly, this approach is useful if the researcher is familiar with the IRB application process, as the prompts scaffold prior learning or past experiences. However, this presupposition is one of three primary limitations of the Pech et al. paper.

The first limitation is that the paper declares that a "better understanding of the primary determinations an IRB is required to make…can help researchers anticipate problematic issues and provide the information relevant to these determinations in their IRB applications." (p. 618). This assertion is problematic because it primes researchers towards anticipating obstacles. Increasing one's understanding of research ethics and federal regulations should be rooted in protecting human subjects, not steering clear of problems. Failure avoidance is not how we should define what a quality IRB application looks like. In their publication on training ethical psychologists, Handelsman et al. (2005) explain that "ethics is the study of right and wrong but is often taught as the study of wrong. Many ethics courses …do not focus on best practices…[and are] limited primarily to learning rules" (p. 59). This sentiment holds true here: a more positive approach to the IRB application experience is necessary.

The second limitation of Pech et al.'s work is the assumption that researchers can anticipate the IRB's concerns. Even if researchers increased their regulatory literacy, as much of the literature suggests they should (see *Addressing Researchers' Regulatory Literacy* section above), this overbroad advice could skew their expectations and overpromise success. It is not the researcher's task to ensure perfection at the outset, especially if there are barriers or knowledge gaps they know they face. Researchers should focus less on anticipating the IRB's questions in isolation and instead seek personalized advice directly from their IRB prior to, or during, drafting their IRB application.

The third, and most impactful, limitation of Pech et al.'s work is that the paper presupposes that a researcher is capable of composing a preliminary application where the primary problems are just that it is vague, inaccurate, or too brief. And that, by merely familiarizing themselves with the regulations, a smoother IRB application process is just ahead. If, due to lack of experience, awareness, time, resources, etc., entire content areas within the IRB application have been omitted (e.g. a scientific rationale for inclusion/exclusion of specific participant groups), this article does not provide an adequate starting point. In other words, this paper assumes the application content satisfying criteria for approval may be included, just in an insufficient way. It does not consider completeness of the application as the most revealing initial attribute of the application.

Ironically, towards the end of the paper, Pech et al. do have a "Preparing a good IRB application" section which gets to the heart of the matter, concluding that:

> "An IRB cannot approve absent or unclear information…An IRB can only approve what it receives. Although an absent questionnaire or unspecified control group may involve minor risks compared with central study interventions, an IRB cannot make such an assumption and approve absent study components...If inconsistent or unclear information is provided, then it would be unclear what an IRB was approving…When in doubt, ask the IRB" (pp. 626-627).

In short, there is a stark difference between an imperfect IRB application and an incomplete IRB application.

**A Lone Definition.** The third paper included is a short survey-based research study authored by Sieber & Baluyot (1992). Despite its brevity, Sieber & Baluyot appear to be the only researchers to explicitly define IRB application quality in the presently available literature.

The aim of their survey, and the resulting paper, was to solicit and prepare content for an upcoming social-behavioral science book. The authors surveyed 102 IRB chairs for common issues facing their IRBs and educational strategies used at their institutions; they received 78 responses. Included in the survey was an "index of protocol adequacy" which sought to determine if IRBs that review biomedical research differed in their views of protocol quality than those that review social-behavioral research. The results state:

> "The following key variables were identified as characterizing generally lower quality protocols: protocol is unclear; protocol shows no apparent faculty supervision (on student protocols); protocol appears thrown together at the last minute; and protocol is treated as a bureaucratic evil, not as a planning tool" (p. 10) (see Figure 3).

The authors report no difference in comparison groups with respect to perceptions of protocol quality however, no statistical data is presented in the paper.

An open-ended question on the survey explored how respondents' IRBs addressed their most common problems. Many of the noteworthy responses reported in the paper relate to improving IRB application quality (though not explicitly stated as such). These educational interventions included: workshops for chairs, deans, and faculty on the process of developing adequate student and faculty applications; a detailed IRB application template with instructions and a checklist; a graduate student assistantship position within the IRB; and offerings such as handouts, seminars, a handbook/guide, and a lending library of books.

The key benefit of this publication is that it appears to be the only source in the literature to explicitly define IRB application quality. A secondary benefit is the identification of educational strategies for supporting IRB application quality. The main limitation of the study is that the author's definition of quality is only briefly mentioned, it is not explored in any great detail, and it focuses on "lower quality protocols" and not high-quality protocols (as this project has).

**Characterization of "Lower Quality Protocols"**

1) Protocol is unclear
2) Protocol shows no apparent faculty supervision (on student protocols)
3) Protocol appears thrown together at the last minute
4) Protocol is treated as a bureaucratic evil, not as a planning tool

*Figure 3 - Sieber & Baluyot (1992)*

While the Avci (2017), Pech et al. (2007), and Sieber & Baluyot (1992) pieces are proximal to my research questions on IRB application quality, large gaps remain in what is understood about what a high quality application looks like, why it matters, the barriers and bridges researchers face in producing quality applications, and how the IRB can effectively promote and support the production of quality applications.

**Why Lack of a Definition of "Quality" is a Problem of Practice**

Federal regulations establish the required criteria for approval for the conduct of human subjects research (45CFR§46.111). Without satisfying this criteria, the IRB cannot approve a proposed research study. Despite the availability of the criteria, the regulations do not provide researchers with a straightforward roadmap of how to prepare a complete, approval-ready IRB application. Further, the regulations do not prescribe how research proposals are submitted to the Institutional Review Board (IRB), nor do they codify the components of a standard IRB application.

Each IRB is required to maintain written operational procedures describing their recordkeeping and decision-making, but can exercise their discretion on the precise mechanism for IRB application submission. Application templates created by IRBs provide researchers with

a functional framework for describing and structuring their research studies. Such templates are the best approximation at a roadmap, as they request information the IRB believes to be the most useful and compelling in satisfying the required regulatory criteria for approval.

Despite the head start provided by the regulations and supported by protocol templates, preparing a quality IRB application remains a challenge. As stated, there are significant gaps in what we know, empirically and descriptively, about this interpretation of quality. To that end, a more nuanced and practical understanding is needed of what both IRBs and researchers consider to be a successful IRB application experience.

The literature claims that the more familiar researchers are with the regulatory approval criteria and how the IRB interprets them, the more successful their IRB application will be and the less likely they are to experience long turnaround times and deferrals (Hale et al., 2011; Page & Nyeboer, 2017; Pech et al., 2007). Alternatively, researchers may argue that their highly-developed scientific/methodological expertise should drive the quality of their IRB applications instead (Binik & Hey, 2019; Klitzman, 2013). Equally, specificity, following instructions, and accurate attention to detail throughout the IRB application may be the key to success. For example, a study conducted by Collen et al. (2019) found that in straightforward retrospective medical record review IRB applications, "almost 60% of protocols were not approved on the first review because of missing, incomplete or contradictory documentation, errors, or omissions in the protocol or application" (p. 992). Discrepancies between researchers and IRB professionals on the concept of quality muddles the definition such that researchers do not know how to achieve quality and IRBs do not know how to define quality.

## Conceptual Framework

### A Reimagined Version of Experiential Education and Transformational Learning Theories

Learning is one of the most intriguing accomplishments of human existence. However, this unique capacity has raised a single core question that has been debated, litigated, and researched throughout human history: how do humans learn? In service of this inquiry, countless theorists, scholars, scientists, and academics have brought their ideas to bear. Standard models of education (e.g., didactic, lecture-based, and passive methods) depict a hierarchical, power-driven dynamic where teachers lead and lecture and students absorb and acquire. Is the passive absorption of information truly learning? Decades of research argue against this style of traditional pedagogy.

Experiential Education and Transformational Learning Theories contribute needed perspectives on how humans learn. Experiential Education Theory describes the environmental aspects of the learning phenomena, while Transformational Learning Theory describes how to design and implement student-centered communities of practice. As a result, a reimagined version of these theories, blending their complementary organizational and applied components, is needed in order to contextualize my problem of practice (Figure 4).

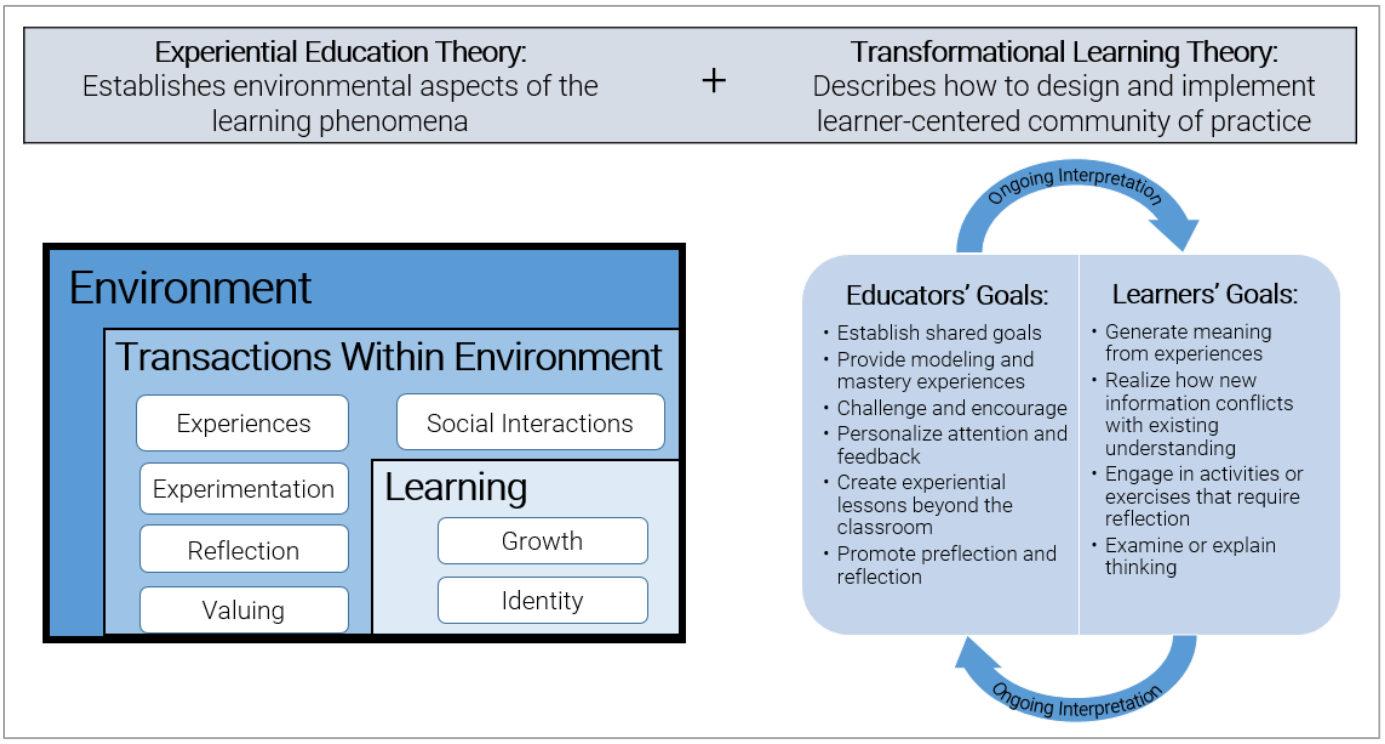


*Figure 4 - A Reimagined Version of Experiential Education and Transformational Learning Theories*

***Experiential Education Theory***

Prolific American philosopher and education reformist John Dewey's educational theory of experience situates the learner in an educative environment with continuity and interaction at its center. Dewey believed that a learner's growth could take many paths and that all learning experiences influenced the conditions of subsequent experiences, opening new environments. Some of those experiences shut down growth, and others foster it. Dewey wrote:

> "If an experience arouses curiosity, strengthens initiative, and sets up desires and purposes that are sufficiently intense to carry a person…every experience is a moving force. Its value can be judged only on the ground of what it moves toward and into" (1938, p. 38).

In pursuit of actualizing environments that foster the learner's growth, educators must interrogate the pedagogical status quo of didactic teaching. Influential Brazilian educational thinker and philosopher, Paulo Freire, identified in his opus, *Pedagogy of the Oppressed*, that "[we] must abandon the educational goal of deposit-making and replace it with the posing of the problems of human beings in their relations with the world" (1970, p. 79). He stated: "liberating education consists in acts of cognition, not transferals of information" (p. 79). Freire's framework emphasizes education as a co-construction between teachers and learners through joint communication, critical intervention, knowledge creation, and sensemaking. To that end, learning is an evolutionary process of continuous transformation with its roots firmly in "the dynamic present" (p. 84).

As this relates to my problem of practice, researchers can be led into new environments that mitigate or ease regulatory and/or administrative burdens, and promote research compliance. The "moving force," as Dewey poetically called it, that research administrators seek to translocate researchers into is one of regulatory compliance. Dewey called on educators as the architects of such environments:

> "A primary responsibility of educators is that they not only be aware of the general principle of the shaping of actual experience by environing conditions, but that they also recognize in the concrete what surroundings are conducive to having experiences that lead to growth. Above all, they should know how to utilize the surroundings, physical and social, that exist so as to extract from them all that they have to contribute to building up experiences that are worthwhile" (1938, p. 49).

Such co-constructed environments can create collaborative pathways between researchers and administrators in service of their mutual goals.

***Transformational Learning Theory***

Drs. George Slavich and Philip Zimbardo, contemporary psychologists, are responsible for Transformational Learning Theory, which "involves creating dynamic relationships between teachers, students, and a shared body of knowledge to promote student learning and personal growth" (2012, p. 569). Slavich and Zimbardo draw substantively on American sociologist Jack Mezirow's Transformation Theory. Mezirow, influenced heavily by Dewey and Freire, developed Transformation Theory as a constructivist approach to adult learning that features the ongoing interpretation and reinterpretation of one's experiences for sensemaking, resulting in learning.

Transformational Learning Theory calls on educators to abandon outmoded teaching models, namely uninterrupted lecture and passive student learning, and instead facilitate learning with problem-solving that maximizes student development (Figure 5).

> "[Educators] accomplish these goals by establishing a shared vision for a course, providing modeling and mastery experiences, challenging and encouraging students, personalizing attention and feedback, creating experiential lessons that transcend the boundaries of the classroom, and promoting ample opportunities for preflection and reflection" (Slavich & Zimbardo, 2012, p. 570).

Fundamental to student-centered learning, and more importantly intellectual and personal growth, is the learner's own role in shaping their experience.

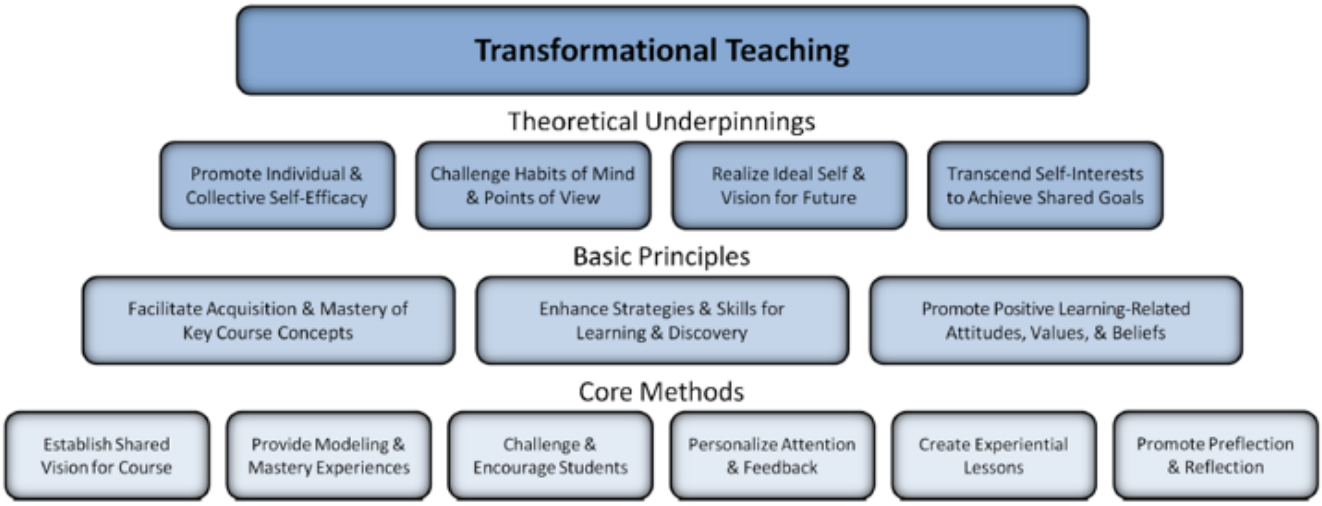


*Figure 5 – Theoretical underpinnings, basic principles, and core methods of transformational teaching*

### *Implications for Use in Educating Researchers*

The centrality of the theoretical models presented here is the constructivist approach to learning. In other words,

> "[learners] generate knowledge and meaning best when they have experiences that lead them to realize how new information conflicts with their prevailing understanding of a concept or idea...Students must do more than just listen to an instructor describe concepts…they must engage in activities or exercises that require them to reflect on their understanding and examine or explain their thinking (Jensen and Lawson 2011; Lord 1997; Stockdale and Williams 2004)" (Slavich & Zimbardo, 2012, p. 574).

Experiential education theory considers learning that extends beyond classroom walls and expands into the real world. Conducting human subjects research is an activity entirely situated in the real world vs. a classroom, with tangible risks and benefits – including life and death. Involving researchers in creating their own learning environments, where they find both support and practical application of research regulations and ethical research principles in the real world, upholds the constructivist approach of a learner engineering their own knowledge. Specifically, this project seeks to establish a shared vision between IRB professionals and researchers for successful IRB application experience.

## Project Questions

Through the following lines of inquiry, this project operationalizes the characteristics of a quality IRB application, establishes barriers and bridges to producing one, and identifies resources needed for researcher's success:

1. What are the characteristics and other determinants of a high-quality human subjects research IRB application?
2. How do IRB professionals and researchers at MGB overlap and differ in their characterization of quality?
3. What resources are needed to assist researchers in producing high-quality human subjects research IRB applications?

## Study Methods and Materials

### Study Design

This study used a qualitative, descriptive, cross-sectional research design to identify individual perspectives on quality IRB applications. An idiographic, individual-focused approach provided a method of inquiry to characterize perceptions of IRB application quality belonging to two participant cohorts: Group 1) MGB IRB Professionals and Group 2) MGB Researchers. The aim of this process was twofold: 1) to see if composite viewpoints for Group 1 and Group 2 could be derived from the opinions of their individual members and 2) to cross-compare the perspectives of Group 1 and Group 2 to identify common or diverging opinions on barriers and bridges to IRB application quality.

There were no direct benefits to participants. However, an operationalized definition of IRB application quality can provide societal and scientific benefits by contributing to the field of human research protection programs. From this understanding, qualitative interviews were selected as the best method to draw conclusions that could:

1. Improve understanding of how IRBs conceptualize quality to ensure adequacy of their review.
2. Develop normative and procedural guidance for how IRBs can identify quality.
3. Develop resources for researchers that include strategies for optimizing the quality of their IRB applications.
4. Devise a roadmap to help prepare researchers for success throughout the lifecycle of the project, provide regulatory support, and promote compliance.
5. Identify overall recommendations for cultivating quality IRB applications.

## Participants

### *Partner Organization*

As noted in the *Organization Context* section above, all participants involved in this study were affiliates of Boston-based, non-profit hospital network, Mass General Brigham (MGB). The MGB Human Research Protection Program (HRPP) provides a shared services model where the research support offices facilitate the administrative, financial, and regulatory requirements of research and sponsored projects received by MGB member institutions. The MGB Institutional Review Boards (IRB) provide oversight for research projects conducted at all 14 of MGB's affiliated member hospitals.

### *Participant Groups (Inclusion Criteria)*

This study includes two participant cohorts: Group 1) MGB IRB Professionals and Group 2) MGB Researchers.

**All participants.** All participants were adults (18+ years old), willing to provide consent, and have firsthand knowledge of the MGB IRB application process based on their respective roles within the MGB research community (i.e., Group 1 has IRB application review experience and Group 2 has experience preparing an IRB application and undergoing the review process).

**Group 1: MGB IRB Professionals.** Includes employees working within the MGB IRB.

**Group 2: MGB Researchers.** 1) Includes affiliates from all 14 MGB member hospitals whose research activities and sponsored projects are subject to the review and approval of the MGB IRB. 2) Includes MGB researchers conducting research involving an intervention or interaction with human subjects. This is an appropriate way to refine Group 2 eligibility, as researchers conducting secondary data analyses research projects, for example, undergo a markedly different IRB application experience and would not be able to provide consonant responses to the research questions posed in this study. See Figure 6 for a diagram of the selection/sampling process for Group 2.

### *Participant Sampling*

**Group 1: MGB IRB Professionals.** All MGB IRB employees were purposively sampled based on their professional skills as IRB staff to provide an in-depth, nuanced description of their IRB application review experiences.

**Group 2: MGB Researchers.** Researchers were purposively sampled based on their ability to provide an in-depth, nuanced description of their IRB application experience. This ability was determined by identifying researchers who had recently received IRB approval for an initial study application.

Once identified, the list of eligible participants underwent a single-stage stratified sampling process where researchers were arranged into two groups: 1) those whose initial

approvals were completed via Expedited IRB review and 2) those whose initial approvals were completed via Full Board IRB review. The distinction between these stratified groups is a regulatory one – Expedited IRB review of minimal risk research is performed by a designated reviewer(s), whereas Full Board IRB review of greater than minimal risk research is performed by a convened panel of IRB members. A simple random sampling process from each strata was used to ensure all eligible Group 2 participants had an equal chance of being selected to participate in this study and to ensure sufficient participation from each strata in the study. See Figure 6 for a diagram of the selection/sampling process for Group 2.

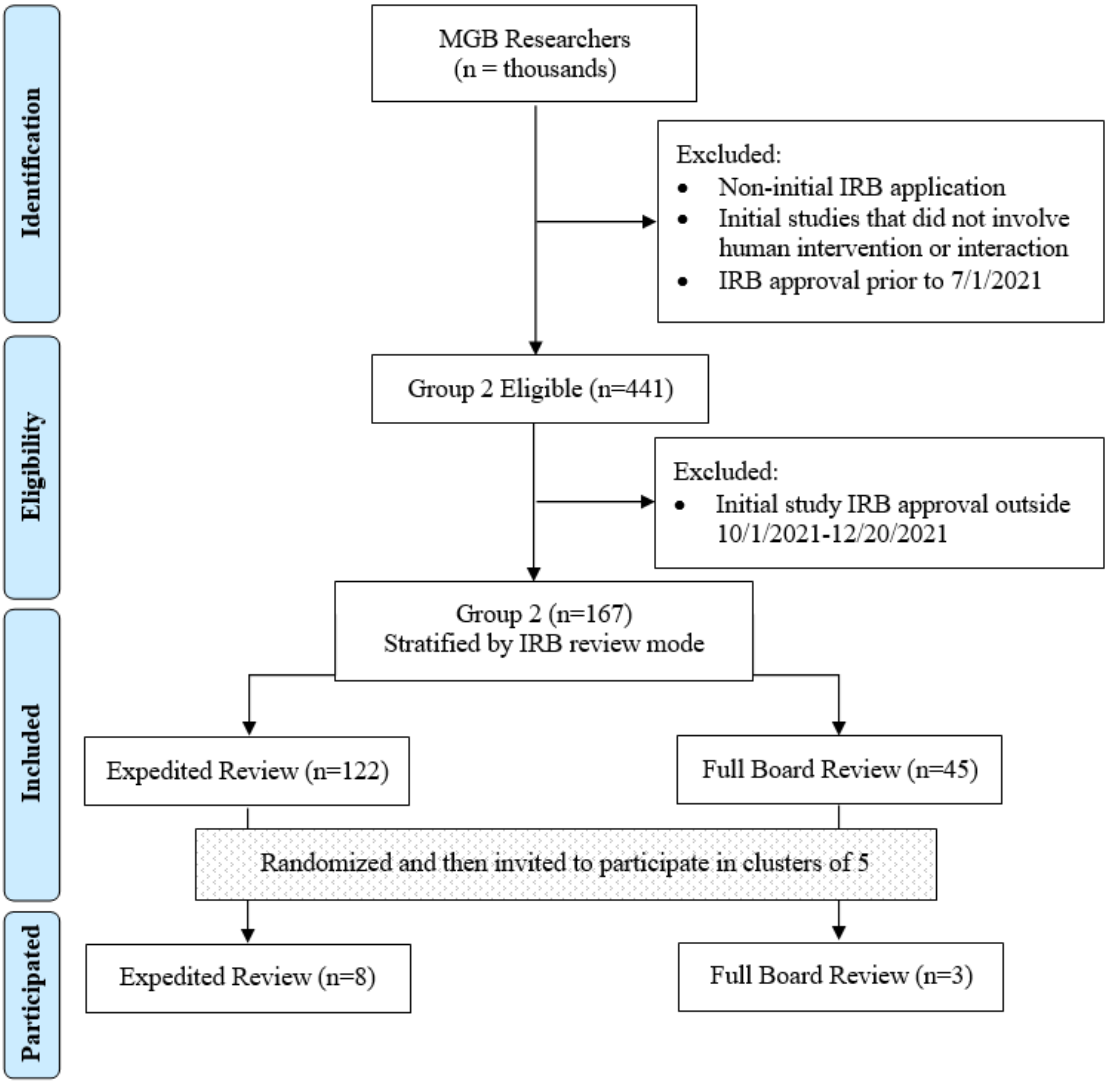


*Figure 6 - MGB Researcher Participant Sampling*

***Participant Recruitment***

The MGB Vice President of Human Research Affairs provided a list of individuals who fit Groups 1 and 2 inclusion criteria, as described above. Groups 1 and 2 were recruited as follows.

**Group 1: MGB IRB Professionals.** I was invited to attend the December 15, 2021 MGB IRB staff meeting to introduce the project and recruit participants. A brief presentation of the

project was given using the recruitment script. The presentation was followed by a question and answer period. After the meeting, I sent a follow up email to all MGB IRB staff on the Group 1 list provided (n=36). The email included a review of the project's aims, study procedures, and a link to an online meeting scheduling platform (Calendly) where those interested could sign up for a one-time interview convenient to them. Because of the small sample size, a voluntary response sampling method was used; i.e., all MGB IRB staff were invited to participate. Reminder emails were sent on sent on January 10, 2022 and March 7, 2022. No incentives were offered for completion.

**Group 2: MGB Researchers.** I was provided with a list of eligible Group 2 participants, as described above and depicted in Figure 6. A total of 167 eligible Group 2 participants were identified from the list (i.e., researchers who secured IRB approval between 10/1/2021-12/20/2021 for an initial study involving an intervention/interaction with human subjects). Group 2 was stratified into sub-groups: 1) researchers whose studies were approved via Expedited IRB review (n=122) and 2) researchers whose studies were approved via Full Board IRB review (n=45).

Expedited and Full Board strata were randomized on January 9, 2022 using random.org. Researchers were invited to participate via email in clusters of 10 individuals at a time (5 from each strata). Cluster recruitment was utilized to manage my time and volume of concurrently interested participants, as well as monitor ongoing thematic saturation of interviews. The recruitment email included a review of the project's aims, study procedures, and a link to an online meeting scheduling platform (Calendly) where those interested could sign up for a one-time interview convenient to them. Recruitment email clusters were sent in the following cadence: Cluster 1 on January 10, 2022, Cluster 2 on January 17, 2022, Cluster 3 on January 24, 2022, and Cluster 4 on January 31, 2022. Reminder emails were not necessary due to the size of the sample. No incentives were offered for completion.

### *Measures and Data Collection*

**Background.** A qualitative research design was selected for this study to obtain rich, individual, nuanced perspectives on the phenomena of IRB application quality. As found in the literature, the concept of quality is domain-specific, stakeholder-relative, and contextually bound. It is challenging to both measure and define. The goal of qualitatively gathering the viewpoints from participants in this study was to operationalize a definition of IRB application quality.

**Development.** Because empirical research on IRB application quality is limited to nonexistent, there are no data collection measures available (validated nor unvalidated; quantitative nor qualitative). As a result, I produced my own data collection instruments for this study. Throughout the interview process, I performed ongoing evaluation of the guides to refine the flow/sequence of questions, improve wording/phrasing, incorporate any overlooked concepts/themes, and adapt the interview length accordingly.

**Data Collection Instruments.** I created two semi-structured qualitative interview guides, one for each participant group. The interview guides include a series of open-ended questions designed to explore the concept of quality, as well as identify the barriers and bridges to producing a quality IRB application. Both interview guides included 14 questions: 9 questions were the same for both groups and 4 questions were customized to the experience-based differences between the cohorts. See Appendix B for Group 1 and Group 2 interview guides.

**A Priori Thematic Mapping/Code List.** A set of a priori themes/codes were generated at the time of the interview guide creation. It was expected that the codes would change and be

refined during data analysis however, the aim of establishing preliminary codes was simply to set a baseline organizational structure for the interview guide key concepts and flow of the interview. This list included 5 broad codes:

1. Theme 0 - Participant Demographics
2. Theme 1 - Characterization of Quality
3. Theme 2 - Process - Identification of Barriers/Bridges to Quality
4. Theme 3 - Process - Supporting and Enhancing Quality (Roadmap)
5. Theme 4 - Impact on IRB Review Quality

**Data Collection.** Semi-structured qualitative interviews were conducted with each participant following my interview guide (the order of questions shifted depending on the flow of the conversation). Interviews were conducted with participants until thematic saturation was achieved. This was accomplished after interviewing 9 MGB IRB Professionals and 11 MGB Researchers; data collection was concluded at that point.

**Analytic Memos.** During the data collection phase, I wrote analytic memos in real-time after each interview. Memoing provided me an opportunity to reflect on each participant, how precisely their responses answered the questions asked, and how each interview compared and contrasted to the others. While memoing, I used cumulative induction to draw initial conclusions about each cohort, develop the coding structure, and assess proximity to thematic saturation. Memos also provided dedicated time to review the interview's flow and feel, and determine what needed to be adjusted before the next interview. Memos were not summaries of each interview, but rather a way for me to begin preparing and organizing how to assemble, cluster, test, and report the data. This intentional reflection led to both sensemaking and sharp conceptual insights in real-time. In sum, memoing satisfied its ultimate goal which was to identify connections among participants, patterns, themes, and concepts to create a network of understanding about my topic.

### *Procedures*

Once participants scheduled an interview via Calendly, I followed up with a confirmation email. The confirmation included an interview calendar invitation with remote video call (Zoom) link, and PDF file attachments of the consent form and interview guide questions. Participants were told they were not expected to prepare in advance, but reviewing the questions before the meeting would give them a sense of the conversation and how they may want to respond. All interviews took place on Zoom to observe existing COVID-19 protocols in place both statewide in Massachusetts and in the MGB network.

Once the participant joined the interview on Zoom, they were first asked for their permission for the interview to be recorded. They were informed this was for data fidelity, transcription integrity, and analytic purposes, and that only I would have access to the recordings. Zoom recordings included both audio and video files, and a full-text transcription of the session was automatically generated afterward based on my Zoom settings. Participants were reminded that their responses would be kept confidential and nothing potentially identifiable would be published without their explicit permission. Study data was managed according to strict security standards; all data was and is stored on my secure, Harvard-provisioned, password-protected laptop. To ensure Zoom file security, I used my Harvard-provisioned Zoom account which includes password protection, required participant waiting room, and recording access available only by granted permission. There are no hard copy or paper study records.

Next, I conducted the consent process which included a review of the information in the consent form (study aims, procedures, voluntary nature of participation, risks, and who to contact with questions) and ample time for questions or clarifications. The participant was again informed that there are major gaps in the existing literature on IRB application quality and the purpose of the study is to explore the concept of "quality" in relation to their role in the MGB research community. Participants were told they could respond in as much or as little detail as they like, that there were no right or wrong answers to the questions, and they could skip any question they did not want to answer.

Once I obtained verbal consent from each participant, the interview began. Each participant was led through their respective interview guide. I employed a semi-structured approach, using active listening to probe further on interesting remarks, to restate participants' responses to verify accuracy, and ensure the flow of questions was logical and non-repetitive. All interviews took between 30 minutes and 1 hour.

### *Ethics Approval*

IRB review was sought at three institutions: 1) Vanderbilt University (where I am a doctoral student), 2) the Harvard T.H. Chan School of Public Health (where I am employed full time as the Associate Director of IRB Operations), and 3) Mass General Brigham (MGB) (where participants were recruited). The Vanderbilt University IRB determined this project was Not Research, viewing the activities as a non-generalizable, site-specific quality improvement project. The Harvard T.H. Chan School of Public Health IRB granted an Exempt human subjects research determination. The Mass General Brigham (MGB) IRB concurred with the Harvard Chan School Exemption; they did not require additional review nor a reliance agreement between institutions. Despite the Vanderbilt IRB's determination, MGB leadership and I agreed that, because MGB is known regionally as an expansive, networked, statewide organization, work with their HRPP/IRB could be generalized to other institutions and does constitute human subjects research that requires IRB oversight. The HRPP operations at each MGB member institution are different (staffing, resources, portfolio size, etc) and the breadth of participants and their responses would not just represent MGB, but each institution as well. It's a bit of a non-traditional route to generalizability, but we believe the outcomes of the study could be applicable to range of other HRPPs.

### *Data Analysis*

**Qualitative Approach.** Qualitative data coding and analysis was performed using the methodology of Miles, Huberman, & Saldaña (2014). This approach is defined as

> "selectively collecting data, comparing and contrasting this material in the quest for patterns or regularities, seeking out more data to support or qualify these emerging clusters, and then gradually drawing inferences from the links between other new data segments and the cumulative set of conceptualizations" (p. 10).

I followed these steps in order, beginning with very broad 1st level codes, expanding their meaning with a specified 2nd level code, and generating 3rd level codes of even greater detail.

**Coding Procedure.** All data coding was performed using MAXQDA software, Analytics Pro 2022 version. The auto-transcript feature was enabled on my instance of Zoom and I received a transcription once each interview concluded. I downloaded these files in real-time and uploaded to MAXQDA, spot checking for data integrity and correcting typos. The transcribed files served as the foundational text used to code the data for thematic analysis.

First-level coding included mapping interview questions to my initial a priori codes (see *Preliminary Thematic Mapping/Code List* section above). During this process it became clear these codes were not nuanced enough and all first-level codes were revised. For example, no initial codes included concepts of training and education; this is where the category of "Support, Training, Education" emerged.

Second-level coding included a review of all interview responses to generate sub-codes supporting the growing theme/pattern identified by the 1st level code. For example, the aforementioned category of "Support, Training, Education" then led to sub-codes such as "Unsuccessful Strategies" and "Successful Strategies."

Third-level coding was performed to itemize the cluster of responses within the 1st and 2nd level codes with descriptive specificity. For example, within the "Support, Training, Education" category, "Successful Strategies" sub-code, I detailed a list of recurring concepts and assertions described by participants which included "Exemplars-models," "Dedicated IRB point person," and "Helpful colleagues-peers," to name just a few (there were 18 in total).

Each step in the coding process was manual and iterative; I did not use any automation to assist with this activity. All 1st, 2nd, and 3rd level coding was conducted after manually reading and re-reading the interview transcripts. See Appendix C for the complete qualitative codebook.

In addition to thematic codes, I assigned codes to identify noteworthy quotes that would be useful to cite directly in this manuscript. Organizing with a "Good Quotes" code allowed me to quickly arrange these excerpts in one document for ease of re-contacting participants. I reached out to 12 participants on July 1, 2022 to request their explicit permission to quote their words in my work. I received permission from all 12 participants.

**Data Analysis.** Analysis was performed using thematic identification of coded qualitative interview data. As such, the analysis presented in this paper is descriptive and not statistical.

Once coding in MAXQDA was complete, I generated a crosstab report that included every code and its frequency, organized by participant cohort. I reviewed each category of data at a time, including all sub-codes, and frequency of the topic across all responses and by cohort. I then cross-compared each category to the interview guide questions and my project questions. As I reviewed the responses by concept and by group, my findings began to emerge.

For example, the first question each participant was asked was to describe the goals of the IRB in their own words. This question was asked to gain a baseline understanding of how each participant perceived the IRB's role and how they prioritized the IRB's goals. From the responses, the "Basic Goals of the IRB" category was created and 8 sub-codes were generated. Using the MAXQDA report, I was able to view all data simultaneously and generate my observations within the spreadsheet. See Figure 7 for this example.

| Categories & CODES | IRB Professionals | Researchers | Total | Observations, Patterns, Connections |
|---|---|---|---|---|
| **Basic Goals of the IRB** | | | | Participants concur on the IRB's primary goals: participant protection, ethical standards, and the assessments of risks/benefits.<br><br>Other notable findings:<br>- Only 1 participant (IRB Professional) indicated educating the research community is a basic goal.<br>- Discrepancy between IRB Professionals & Researchers on regulatory compliance being a basic goal (not surprising). |
| Participant protections | 5 | 6 | 11 | |
| Follow ethical standards | 5 | 5 | 10 | |
| Regulatory compliance | 5 | 2 | 7 | |
| Risk/benefit assessment | 4 | 3 | 7 | |
| Facilitate research | 2 | 2 | 4 | |
| Review the science | 2 | 1 | 3 | |
| Help/assist researchers | 2 | 1 | 3 | |
| Equitable subject selection | 1 | 1 | 2 | |
| Ensure participant comprehension | 0 | 1 | 1 | |
| Institutional protection | 0 | 1 | 1 | |
| Education | 1 | 0 | 1 | |

*Figure 7 - Example of data analysis process*

I completed this process for each coded category, identifying and extrapolating themes and concepts within each category and then across categories where they were interrelated (e.g. experience was a determinant of quality, but also a bridge to quality). I then took my observation notes recorded within the MAXQDA report and expanded the narrative within the Findings section. I did have data, codes, and analysis that were ultimately not relevant and, thus, not included in this paper.

## Brief Descriptive Summary of Results

### Participants

Twenty qualitative interviews with MGB-affiliates were conducted for this study. Thematic saturation was accomplished after interviewing 9 MGB IRB Professionals and 11 MGB Researchers, and data collection was concluded at that point.

There are no eligibility or descriptive sample characteristics for the MGB IRB Professionals cohort, aside from their employment as MGB IRB staff. Brief descriptive sample characteristics for the MGB Researchers cohort, including stratification by recent IRB review and MGB affiliation, are summarized in Table 2.

| **MGB Researcher Participants (n=11)** | |
|---|---|
| Most Recent IRB Review | Expedited, n=8 |
| | Full Board, n=3 |
| MGB Institutional Affiliation | Mass General Hospital, n=6 |
| | Brigham & Women's Hospital, n=4 |
| | McLean Hospital, n=1 |

*Table 2 – MGB Participant Sample Characteristics*

### Summary of Thematic Analysis

Qualitative analysis generated 34 categories within 3 levels of coding: 1) 8 broad categories set during the first round of coding to establish "parent" level codes, 2) 14 sub-codes supporting the growing theme(s)/pattern(s) identified by the 1st level code, and 3) 12 itemized clusters within the 1st and 2nd level codes establishing descriptive specificity. This analysis produced a total of 923 original coded segments of interview transcript text.

### Beginning with the Basics

Each interview began by asking participants to describe the goals of the IRB in their own words. Indeed all participants had working knowledge of this topic by virtue of the inclusion criteria of the study (i.e. either IRB employees or researchers who recently obtained IRB approval); however, this was an important tone-setting reference point for how each participant perceived and prioritized the IRB's work.

All participants concurred that the IRB's primary goals are ensuring participant safety and protection, upholding ethical standards of research, and assessing the risks and benefits of human subjects research. There was a slight discrepancy between the number of IRB Professionals and Researchers who identified regulatory compliance as a basic goal however, this is not surprising given the predominant role the regulations play in an IRB Professionals' occupational practice. Notably, only one participant (IRB Professional) indicated that educating the research community is a basic goal of the IRB.

## Findings

Findings have been organized by Project Questions to structure the body of evidence generated by this project.

### Project Question 1: What are the characteristics and other determinants of a high-quality human subjects research IRB application?

There are two ways that this project sought to characterize IRB application quality. The first was to ask participants to describe the attributes of a high quality and poor quality application. The second was to ask each participant's opinion on the determinants of application quality. These two dimensions provide a composite picture of "quality" - defining the levels of quality establishes a successful model, whereas identifying determinants of quality can inform ways to achieve that model.

#### *Finding 1 – Characterization of a High Quality IRB Application.*

Participants in both cohorts uniformly characterized a high quality IRB application with 7 descriptors. In order of prevalence, the seven are: 1) attention to detail, 2) complete, 3) well-written, 4) evident demonstration of effort, 5) organized, 6) sound science, and 7) clear purpose.

#### *Finding 2 – Characterization of a Poor Quality IRB Application.*

Participants in both cohorts uniformly characterized a poor quality IRB application with 7 descriptors. In order of prevalence, the seven are: 1) incomplete/lacking sufficient detail, 2) experience of submitter, 3) poorly organized, 4) lack of proofreading, 5) absence of PI oversight/direct involvement, 6) lack of training/resources, and 7) inconsistencies throughout the application.

#### *Finding 3 – Four Determinants of Impact.*

A primary goal of this project was to explore if and how researchers' regulatory literacy impacts IRB application quality. However, regulatory knowledge is not an isolated skillset when producing an IRB application. There are in fact four interrelated proficiencies that may be determinative of application quality: 1) regulations, 2) ethics, 3) science, and 4) administrative procedures.

**Regulations.** Researchers recognize the value and need for research regulations, especially when the regulations dictate researcher responsibilities, but overall defer to the IRB's expertise in this area as regulatory experts. IRB Professionals acknowledged that it is rare for researchers to have regulatory knowledge in general, but they don't necessarily expect them to. This calls into question whether or not researcher's regulatory knowledge 1) is necessary or 2) impacts quality.

Pech (2007) claims that

> "when researchers are familiar with [regulatory criteria for approval] and how they may be interpreted by an IRB, they can craft an IRB application that anticipates many of the questions that arise during IRB deliberations, thus avoiding deferrals or lengthy requests for protocol modifications or clarifications" (p. 618).

However, the findings of this project do not support this claim. In the view of MGB IRB Professionals, regulatory knowledge on the researcher's part is not paramount. The results of this study found that communication and cooperation are much more determinative of IRB approval, and a quality application, than regulatory knowledge. In fact, many IRB professionals acknowledge regulatory expertise is our jobs, not the researchers.

> "I think that we expect that researchers will come in without a great grasp on the regulatory piece and so I think we're used to kind of playing that role. So actually, I think that might be less of an impediment [to a quality application] than just understanding how to conduct your research in the environment in which you want to conduct it." – IRB Professional, Participant 2

It is common that IRB application materials include regulatory phrases, words, and citations to elicit certain responses from researchers. However, if researchers typically do not have regulatory literacy, it is an open question whether it is effective to use regulations in this way. Both IRB Professionals and Researchers did feel that regulatory language or technical jargon within the IRB application should be reworded or written in lay language to enhance researcher comprehension. Researchers suggested that if regulatory terms are needed in the IRB application, that they should be accompanied by a plain-language definition.

> "I think sometimes we come...from such a regulatory standpoint like, is our view narrow? … Are we thinking about it from such a narrow lens that we're only concerned [with] the regulations when designing the applications, but maybe not making it easy for researchers to…provide an answer to us." – IRB Professional, Participant 10

> “We shouldn't be asking a researcher - is your research study Exempt or not? We need to ask the questions so that we can make that assessment, and not necessarily use the regulatory language. Actually just ask the question that is going to get you the answer you need...I think part of having a quality application is us doing a better job designing our application.” – IRB Professional, Participant 3

**Ethics.** Notably, there were no independent mentions that ethics superseded any other determinants when this topic was explored with participants. Each individual I interviewed recognized ethics as an unmistakable and non-negotiable component of an IRB application.

**Science.** As noted above, participants in this study characterized a high quality IRB application as one demonstrating sound science. In order to understand this finding, briefly unpacking what “the science” means here is worthwhile.

It has been long debated whether scientific review is part of the IRB’s purview, or if IRB review should strictly focus on regulations and ethics. Binik & Hey (2019) object to divorcing scientific review from IRB review: “a strict division-of-labor system is not tenable. This is because an ethics committee cannot perform its risk-benefit assessments properly without understanding and scrutinizing a study’s design” (p. 5). Tensions on this issue persist between researchers and IRBs.

From my view, if “the science” (i.e. the field of study, design of a study, and/or procedures within the study) is a factor in calculating the risk/benefit ratio of the research, it *is* the IRB’s job to review. For example, the stepped wedge cluster randomized trial (SW-CRT) is a novel research design where participant clusters are exposed to the research intervention towards the end, versus the beginning, of a study. Proposing to use a SW-CRT design for a mental health intervention research study would likely prompt the IRB to conduct a very close review of that design choice. That said, in my experience, IRBs are not intentionally pursuing scientific review, nor do they want to. It is only when the science impacts participants’ safety, rights, and welfare that the IRB will examine it closely.

Consistent with the vast body of literature on this topic, MGB Researchers expressed concerns about IRB scientific review overreach and doubts about the IRB’s level of scientific expertise when doing so. For example, topics such as genomics, specific disease states, and clinical standards of care were cited as areas where IRB expertise may be incomplete. However, this is a common misconception among researchers. A recent publication established that it is not possible for IRBs to have complete domain expertise for every conceivable application they may receive (Serpico et al., 2022). The federal regulations require IRB members have requisite expertise “to promote complete and adequate review of research activities commonly conducted [at their] institution” (HHS, 2018, section 107).

MGB Researchers also expressed concern about lay members/non-scientific members making novice judgements about the science. Again, in my experience, this is precisely the reason the regulations *require* IRBs to include “at least one member whose primary concerns are in nonscientific areas” (HHS, 2018, section 107): because they provide checks and balances analog to a participant, and can increase the accessibility and readability of dense study documents like the consent form. Finally, emerging research on IRB expertise, and engagement

of external consultants when needed, suggests IRBs do recognize when they need additional assistance with reviews, it just occurs infrequently (Serpico et al., 2022).

**Administrative Procedures.** In my view, administrative procedures encompass the clerical and mechanistic components of the IRB application experience (e.g. producing an application, navigating an online submission portal, following institutional policies, communicating with the IRB, using templates and resources). This component has many moving parts, requiring thoughtful coordination and advanced preparation.

> “It's just like a research paper...you need to gather all the data points before you then can write your paper...you need to figure out the bundle of steps you need to take to successfully submit a protocol for review.” – IRB Professional, Participant 4

Of the four determinants, administrative knowledge presented itself throughout the interviews as the most complex capacity impacting IRB application quality. It was also the lowest ranked of the four determinants in terms of priority. Administrative procedures appear to be both the biggest source of frustration for MGB Researchers, but also can be the biggest centerpiece of learning during the IRB application experience. One quote exemplifies these competing interests, including the opportunities that administrative savviness may present:

> “Going back to the procedural thing...we were planning on buying a piece of equipment that was *identical* to equipment that we already had … [The IRB] said well 'we can't approve this until you get the new equipment'. But it's *the exact same thing* ... [It's] just one of those frustrating things as a researcher. Can [the IRB] conditionally accept the proposal, and then say 'you can't do this specific part until it's approved'? If everything is tied into [the equipment approval], then it holds everything else up. But at the same time, my PI would have said 'Okay, well then just take it out and then submit [it later as] an amendment.' That's a level of administrative knowledge to have...because you're thinking [the IRB application] needs to be the whole thing and be done. And that's maybe what you think quality is, but quality can also be [submitting] a timely amendment … I think having knowledge of how things work is probably equally as important as having good science.” – Researcher, Participant 13

MGB Researchers described administrative hold-ups during IRB review as “tedious”, “overly bureaucratic”, “annoying”, “a struggle”, and “time-consuming.” As a result, these frustrations motivate workarounds. 25% of participants acknowledged the most practiced strategy used to circumvent these obstacles is to submit the IRB application, in whatever state it is in, and see how IRB review goes. The thinking is that once the application is in the IRB’s hands, it is their task to make it approval-ready.

> “It's very challenging to get an answer quickly [from the IRB], maybe several weeks...and so usually it's just easier to submit what you think might be the wrong thing, but you tend to get an answer back quicker by going through the process than by waiting for somebody to respond to an email.” – Researcher, Participant 17

> “Some people would just throw it over the fence [i.e. submit the application] and see what happens on the other side. They say 'Okay, I'm gonna fill this in quickly and see what kind of comments I get back [from the IRB], and I'll see if I did a good job or I didn't.” – IRB Professional, Participant 4

> “I've heard people say things like 'Oh, it doesn't matter, just get it into the IRB and they'll fix it for you.' This can really end up slowing down the process, for the IRB and the investigator. We would rather collaborate with investigators prior to their submission to help them submit as quality an application as possible from the outset.” – IRB Professional, Participant 3

This is a problematic strategy because it demonstrates how the quality of an IRB application impacts the quality of review it receives. First, this practice shifts the labor and responsibility for a quality IRB application from the researcher to the IRB. Second, this stance can compromise cooperation; if researchers view the IRB as their fixer, and not their partner, they may be inherently devaluing the skills required to produce a high quality application. Finally, any IRB application submitted under duress is unlikely to possess the 7 attributes of a high quality IRB application identified above.

**Relationships Between Determinants.** The four determinants impacting IRB application quality - 1) regulations, 2) ethics, 3) science, and 4) administrative procedures – are undoubtedly interrelated and complimentary. These four determinants can complicate IRB review and the perceptions of application quality by presenting a causality dilemma: deficiencies in any combination of the four may inherently compromise the others, and then present overall as a poor quality IRB application. For example, if researchers cannot interpret the regulatory jargon used in the application template, and respond incorrectly as a result, the IRB may perceive that as a quality issue.

> “I think it's a misstep when people think that one component supersedes the others (ethics, scientific considerations, or administrative knowledge) because...they all contribute to one another. They all elevate each other when the bar is high, and they can also take away from each other...when that quality is compromised by not fully thinking through an issue.” – IRB Professional, Participant 20

> “I think that [researchers] should cooperate with us on regulatory and administrative issues the way we cooperate with them on scientific and ethical ones.” – IRB Professional, Participant 6

> “We're all just trying to get the job done but we're not necessarily helping each other get the job done.” – Researcher, Participant 12

***Finding 4 – Biggest Determinant of a High Quality IRB Application.***

In addition to the four determinants discussed above, all participants interviewed were asked what they believed was the *biggest* determinant of IRB application quality. Participants in both cohorts converged on the same determinant of IRB application quality: the degree to which the application clearly describes the study from start-to-finish. This project establishes that, while MGB IRB Professionals and Researchers differ in the level of detail they believed to be sufficient within an IRB application, both cohorts unequivocally recognize that an appropriate level of specificity is required to obtain IRB approval and, as such, is the primary determinant of a quality application.

Per federal regulations, IRBs are composed of members of varying backgrounds, qualifications, expertise, and experiences. This variation is intentional; IRB members must marshal their interdisciplinary perspectives when reviewing human subjects research to ensure regulatory, ethical, scientific, and administrative standards have been met. As such, a start-to-finish accounting of the entire study requires a written description all members can understand, regardless of their role on the IRB (e.g., scientists, non-scientists, laypersons, subject matter experts). To produce a complete and thorough description of study activities, as well as the participant experience, is an achievement in quality because it means all IRB members can apply the regulatory criteria for approval to what they have read, and find such criteria is definitively met.

Representation of both study activities, and what the participant will experience, is critical and they are different pieces of the application (e.g. study activities are not limited to participant interactions; they involve secure data storage, record retention, reporting non-compliance, statistical analysis plans, dissemination of study results, etc). The degree to which researchers accomplish the goal of an understandable, comprehensive description of the study is a demonstration of quality because it directly determines how many questions the IRB will ask.

In other words, a high quality IRB application is one without ambiguity, inconsistencies, or gaps, and does not require clarifications to bring additional clarity or precision to the proposal.

Participants in both cohorts also mutually established that the ability to produce a complete start-to-finish accounting of a study has a sub-determinant: researcher experience. Experience is a multidimensional determinant; it encompasses having gone through the application process before, applying prior learning from those experiences, an increased ability to anticipate what the IRB is looking for, familiarity with the application system and templates, understanding of institutional policy requirements, greater understanding of the formative work that goes into application preparation, and a level of comfort in navigating the process.

Researcher experience and application thoroughness are interrelated and complementary, just as the four determinants of regulations, ethics, science, and administrative procedures. When all are present in harmony, application quality increases. Two examples from this project highlight this finding:

1. During the interviews, I asked MGB Researchers, when the IRB has requested additional information from them, was that information on hand or did the request take them completely by surprise. All MGB Researchers reported that the IRB's questions did not take them by surprise; they had the answers at hand but omitted details because they felt they were not relevant, they weren't prompted on the application, or it was simply an oversight. This finding suggests that thoroughness is not unreachable; researchers have the information the IRB needs but may lack the experience to be judicious about which pieces of that information are necessary and which are superfluous.
2. New researchers obviously will not enjoy the benefits of prior IRB application experience however, in the absence of experience, new researchers can refer to features of a high quality application and achieve that outcome in other ways. Another determinant of a high quality application is the specificity with which the researcher can describe the study in words, as it is conducted, from start to finish. A new researcher is capable of using that determinant to produce a quality IRB application regardless of their prior experience.

***Finding 5 – The Barriers and Bridges to IRB Application Quality.***

In addition to characterizations and determinants of quality, this project sought to understand the root causes that both impede and promote quality IRB application preparation. All participants were asked to identify both the barriers and bridges to producing a quality IRB application.

**Barriers.** Remarkably, 85% of all participants interviewed reported that the design, content, and frequency of changes to the application materials presents a barrier to producing a quality application. This includes difficulties using the website, lack of helpful instructions, and not being able to easily find all pieces of the application. Consistently MGB IRB Professionals noted that more needs to be done internally to strengthen these materials and consistently evaluate them.

> “I think that's something that maybe IRBs could do a better job of in general … We all have an application and, all of a sudden, you look up and realize you've used this application for 15 years and things [have] changed. And we haven't been … looking internally at what creates a quality application and submission. Well, part of that is how are we collecting information, how are we asking for it? And I think we could all probably do a better job at more consistently, or at least more regularly, taking a look at our internal documentation and giving it an overhaul or just revamp and finding certain questions that needs to be rewritten here and there.” – IRB Professional, Participant 6

MGB Researchers agree that user experience influences quality, and the design/format of the application plays a fundamental role. There are clear interdependencies between user-friendly application materials, expectations of the IRB, details provided by the researcher, difficulties getting/finding IRB help, and the resulting IRB application. These obstacles, cumulatively, don’t just represent a barrier to application quality, they can constrain research, precipitate errors, and perpetuate negative attitudes towards the IRB without adding substantive protections to human subjects.

> “The science should be somewhat sound, they just funded it! So, you know, there's more of a kind of like ‘let's just get this done’ feeling. Especially when...I have to start writing the next [grant/IRB application] so I can't labor over this... I feel like the barriers are a little bit [in] the formatting. Maybe [it’s not something] even the IRB can change, it's just...the more times we repackage things, the more error there might be in cutting and pasting [from a grant proposal to an IRB application]...And there's just something to the mentality that just feels more soul sucking...Because every single attachment that goes along with it - you're like, how do I find the right place, put it in here, say it in the right way...Then [in] some of the forms...I feel like I'm pasting in the same thing...What do you want in this section that's different from that section? So some of it is...we don't necessarily know as much as we should know. But sometimes...we're moving too quickly to where like there's a subtle difference between question 3 and question 3a, and we're not cued into it.” – Researcher, Participant 12

> “The biggest barrier to completing quality applications could be the quality of the application itself.” – IRB Professional, Participant 10

Another common barrier cited was burden caused by administrative hold ups. This included concerns ranging from coordinating reliance agreements, lengthy ancillary reviews, executing data use agreements, determining which IRB to submit to when researchers have dual

affiliations, efficiencies promised by the Revised Common Rule that haven't materialized, usage of too many acronyms, and uploading application documents incorrectly.

In addition to the application itself and administrative burdens, participants identified other consequential barriers to application quality in general areas of concern such as lack of experience, resources, staffing, and time.

**Bridges.** Over 70% of MGB Researchers indicated that having a dedicated IRB point person is both the most successful support strategy *and* most impactful bridge to IRB application quality. This finding is interconnected with other observations MGB Researchers felt were bridges to quality, including the benefits of real-time IRB assistance, transparency on the application's progression at any given point in the workflow, and an efficient initial triage of new IRB applications. MGB IRB Professionals' responses were in concordance; over 60% of IRB Professionals interviewed indicated that connecting with the IRB prior to submitting an application is the most pragmatic and beneficial bridge to quality.

Additionally, there were a subset of bridges to quality identified solely by MGB Researchers. These suggestions were not raised in large numbers but are nonetheless worth mentioning, as they appear to be emergent themes expressed by this participant cohort only. These sub-bridges to quality include ensuring the IRB has adequate expertise to conduct their reviews, paying IRB members for their service to incentivize them, and conducting faster reviews. A full analysis of how these offerings are, in fact, bridges to quality is beyond the scope of this project and requires more in-depth study to substantiate.

Other bridges to IRB application quality, as identified by both participant cohorts, align with findings from other areas of this project, including a researcher's prior IRB application experience, the IRB providing as transparent and complete a review as possible, and the implementation of an Exemplar Library.

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## Project Question 2: How do IRB Professionals and Researchers at MGB overlap and differ in their characterization of quality?

The intersections and divergences between MGB IRB Professionals' and Researchers' opinions on quality were interwoven throughout the whole project. That said, the three most compelling areas of overlap and contrast are the application as an indicator of confidence, how quality leads to "easier" IRB review, and the necessary level of application details.

### *Finding 6 – Three Focal Points of Overlapping and Contrasting Perceptions of Quality at MGB.*

**The Application as an Indicator of Confidence.** One overlapping theme among participants suggested that the quality of the IRB application may be analogous to the quality of how the research is carried out. 40% of participants (evenly split by MGB IRB Professionals and Researchers) raised the point that if/when IRB application quality is low, it may be indicative of other causes for concern (e.g. a poorly run lab, overstretched Principal Investigator, similar struggles with grant and publication submissions, rushing, willingness to engage and cooperate with the IRB). If so, such issues may be pieced together and give the perception of bigger, cumulative problems. More importantly, it may call into question how well the research itself

will be conducted. In other words, the presentation of the application itself is a reflection of its submitter, and a poor quality application may lower the IRB's confidence in the study team.

> "If you are super responsive and you are prioritizing your submission and you're answering all our questions, then I think it's hard not to assume that you're probably going to conduct your research at a higher level. Or, I'm going to expect that the quality kind of carries throughout even though I don't see that in practice. [But] that might actually be kind of an inherent misconception for me...[because] perhaps I am assuming something's going to go really well if I've had a positive experience with you through the IRB process." – IRB Professional, Participant 2

> "I think the presentation [of the application] is a reflection of the researcher themselves. And if they can't even put together an IRB application in an organized way, then what does that say about their data collection, their data storage, checks that their data integrity is intact? ... Understandably, some people are putting in IRB applications really quickly because they need it for funding or whatever, but I think that care needs to be taken up front so that you don't run into issues down the line. I do think that the quality of an application and the organization of an application does reflect on how the study itself might be conducted." – Researcher, Participant 17

**Quality Leads to "Easier" IRB Review.** Both MGB IRB Professionals and Researchers referred to some version of the "garbage in, garbage out" maxim when asked how IRB application quality impacts IRB review quality. Consistently participants pointed out that the higher the quality of the application, the easier IRB review will be. "Easier" in the interviews was described as quicker review time, fewer questions from the IRB, simpler requests for revisions, and smoother interactions between the IRB and researchers. Participants reasoned that a high quality IRB application will receive "easier" IRB review because it will clearly meet the regulatory criteria for approval, and that clarity will be evident to the IRB. This is consistent with the finding that the biggest determinant of application quality is its thoroughness.

> “We're just trying to get to the bottom of exactly how the study is conducted and what's involved...[when the IRB has] to really dig in, they are going to unearth more questions, whether appropriate or not. Because now they're in the position of having to go through these documents with a fine tooth comb because they're just trying to fully understand everything or make sure everything matches up...When someone's really filled out that section of our application well, and then their supporting information in the detailed protocol that reflects that, we can just look at it and assess it and move on...but when you're not provided all those details up front, we're going to end up having 100 questions - and that's just one area one tiny piece of your application.” – IRB Professional, Participant 2

An astute point raised by 30% of MGB IRB Professionals was that “garbage in, garbage out” starts with the IRB's application template. MGB IRB Professionals agreed that a poorly structured IRB application template, one that does not include enough instructions and is difficult to navigate, will lend itself to a poor end product from researchers.

> “On the IRB's end...how are we framing our [application] questions? Is it a poorly worded question, where we're seeing one thing up here and something else that's contradicting that in another question, form, or application? ... The IRB obviously [needs to] present the appropriate questions and application format. [For example], as yes/no [questions], or do we want them to fill out text? Having an idea of how we want to get that information from researchers, and then being able to explain what is it that we're asking here, with each question.” – IRB Professional, Participant 10

> “An application is only as good as the questions that you ask. Researchers do not necessarily know what the IRB needs to make their determinations, and applications designed as 'guess what I'm thinking' are destined to not elicit the information needed. I think we [IRB professionals] have an obligation to do our part. In a collaborative way, we have to clearly outline what we need in an application and then a researcher has an obligation to make that complete.” – IRB Professional, Participant 3

**Devil in the Details.** One finding where MGB IRB Professionals and Researchers distinctly differed was the level of detail they believed to be sufficient within an IRB application. MGB IRB Professionals asserted that more detail is better in basically all instances, whereas MGB Researchers described their association of quality with being concise and streamlined.

My interpretation of this difference is that MGB IRB Professionals believe more detail is better because it provides the most complete description of the study from start to finish - which

has been established as the biggest determinant of application quality. MGB Researchers, on the other hand, believe that a succinct representation of their work is best because considerable detail may invite IRB nitpicking and additional scrutiny.

> "It depends on what [level of detail] the institutional review board demands of us, [and] what [level of detail] is required to meet the FDA and NIH is standards of ethics and safety… A quality IRB submission is one that is clear, concise and not overly detailed but makes it clear, in a stepwise fashion, what that [participant is] going to go through." – Researcher, Participant 16

This perception should be challenged for several reasons. First, as established in this project, a high quality IRB application is one that provides a complete description of the study from start to finish. Succinct or not, Researchers may still open themselves up to scrutiny if their IRB application contains gaps, errors, and inconsistencies, and thus, presents as a poor quality application. Second, MGB Researchers admitted they simply may not know what amount of detail is needed or enough. Feeling overly scrutinized can be one outcome of this knowledge gap, but feeling empowered and educated can be another. As noted above, a start to finish description of study activities and participant experience are the two critical pieces of the IRB application, but they are distinctly different. Study activities are not limited to participant interactions; they involve other components such as secure data storage, record retention, reporting non-compliance, statistical analysis plans, dissemination of study results, and many more. Again, if such details are omitted, this will prompt numerous questions from the IRB. Third, the IRB's charge is to protect the rights and welfare of human subjects. Fulfilling this mandate is not performed uniformly across all research; it is highly dependent on the project's complexities, risk level, and potential risks/harms to participants. It may be an inherent misconception to assume a complex research study can be explained succinctly while also providing an adequate level of detail.

> "We see such a wide variety of research so, unfortunately, I think the more complex a study is, and the more we have to vet the risk/benefit, the more important the quality of the actual application is. That might not be fair but it points to the complexity of submissions. If we have simple submissions and simple studies [e.g. questionnaires, medical record review, analyzing aggregate level data], I think there's a little bit more leeway...The more complex something is, and the more areas of the research there are for us to dive into, we're going to dive into them and question. So it might be an unfair bar to hold complex studies to, but I do think when there's more meat on the bone, there's more that's fair game [for the IRB to review]." – IRB Professional, Participant 2

For example, with a greater than minimal risk study such as a phase 1 clinical drug trial, the study procedures will be complex and must be extremely clear in the IRB application. The IRB will form this expectation as soon as they understand the high level purpose of the study. As

such, the IRB's ability to apply regulatory approval criteria is dependent on the level of detail provided about that specific phase 1 trial. If that information is absent, the IRB will immediately take note and raise questions.

Researchers may call that nitpicking, but to the IRB it is part of their charge to conduct such fact-finding and information gathering. Lack of detail in the application can produce misunderstandings (e.g. due to overstating the research, using overly complex scientific and/or medical jargon), which can lead to miscommunication and additional layers of inspection. MGB IRB Professionals recognized that these inquiries can resemble nitpicking and feel personal. This divide between the IRB and researchers is common, has downstream implications for IRB review quality, and can perpetuate tensions between stakeholders.

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**Project Question 3: What resources are needed to assist researchers in producing high-quality human subjects research IRB applications?**

Characterizing the attributes and determinants of a high quality IRB application brings critical awareness to what such a final product should look like – but can only go so far. The next step is to construct a practical roadmap to achieve that goal. An exploration of existing IRB support services and resources is critical to understanding if the underlying pedagogy of those models is effective or not. To that end, MGB IRB Professionals and Researchers were asked about what IRB-related education/training strategies are the most unsuccessful and successful, and what support is in place to assist researchers in producing a quality IRB application.

***Finding 7 – Unsuccessful Support Strategies in Achieving a Quality IRB Application.***

**General IRB Training.** Over 50% of all participants said that the #1 unsuccessful education strategy when it comes to IRB application preparation is general or basic IRB training. The specific reasons cited were voluminous. The primary concern with this approach is that basics trainings are not protocol-specific and thusly are unhelpful. Basics training is overbroad and doesn't provide enough depth or specificity to produce a quality application, nor does it provide enough direct attention or designated support to the researcher or their needs. When researchers do attend such trainings, they find it difficult to apply basic training concepts when completing their application because basics are not the issue. Basics training provides a foundation for understand the genesis of human subjects protections and the organizational role of the IRB, but cannot possibly provide a nuanced or focused set of tools for application preparation. Additionally, several participants noted that CITI Training was problematic for the same reasons; its focus is at too high level and is not a resource for producing a quality IRB application.

From a practical standpoint, scheduled trainings are time-bound and may occur before or after a researcher needs them. As time is a barrier to producing a quality application, scheduling and timing impact training as well. Researchers reported basics trainings not being an efficient use of their time; instead, they would prefer a one-on-one consultation. Finally, basics trainings can be dense and cause information/cognitive overload for attendees.

**Frustrating Technology.** 50% of all participants noted that it is not helpful when researchers are referred to the website, links, help desk, or general office email address for

resources only to realize they cannot find the content, these resources are difficult to navigate, links are broken, the content is out of date, or the sites refer to themselves in circuitous ways that take them off track.

**Ineffective Customer Service.** With respect to specific support from the MGB IRB/HRPP, over 50% of all study participants described that a lack of response from the IRB, and difficulties getting human help, even though this is offered, is ineffective and unsupportive.

> "Lack of [researcher's] knowledge really stems from a lack of communication. If you're going to come up with the rules, you have to be ready to explain those rules. The reason people are asking these questions, or are having problems, is because the information isn't clear. And if it's not clear, then there has to be a way to get that sort of help in a reasonable time frame." – Researcher, Participant 13

In sum, unsuccessful IRB training and support strategies are consequential because, as discovered in this project, they lead to workarounds, disengagement, and aggravation. Simple things like website navigation and broken links unnecessarily jeopardize IRB application quality. Placing a heavy emphasis on overbroad IRB training may convey that such trainings are more important than individual, project specific-consultation. It may also reinforce to researchers that only a basic appreciation of IRB topics is necessary for success. These frustrations can cause researchers to sidestep the IRB, consulting their peers or other research labs instead. Exasperated researchers also submit poor quality IRB applications because they see it as the only way to get the IRB's attention.

The IRB is uniquely poised to excel in creating supportive learning environments for researchers and shaping ideal application-writing habits. Because we know researchers would prefer more direct assistance from the IRB, ineffective training could be an avoidable drain on time, staff, and resources.

### *Finding 8 – Successful Support Strategies in Achieving a Quality IRB Application.*

**Dedicated IRB Point Person.** MGB Researchers overwhelming want a dedicated IRB point person that they can contact for IRB application assistance, and whom they know and trust. I have experienced the benefits of this organizational structure firsthand, as this is how my team operates (in fact we won an award from the Health Improvement Institute in 2014 for structuring our office this way). Direct benefits of this model are that IRB staff grow their review skill set and they gain exposure to their assigned departments' field(s) of study. In these partnerships, IRB staff and researchers form strong trusting relationships. When IRB staff are responsible for an entire department's portfolio they don't routinize their reviews. On the contrary, IRB staff become extremely well versed in each researcher's portfolio including frequent populations studied, research methods used, study locations and local contexts, specific terminology and scientific procedures, and broadly the larger research questions being asked by the field of study.

Drawbacks to this model can include not having a staff with an extensive enough background needed for such a job design. Another drawback can be that needy researchers

monopolize the time of one staff member by frequently asking them questions, scheduling meetings, and sending them emails. Further, the concept of a dedicated IRB point person can be a culture shift and takes deliberate planning and infrastructure to succeed.

**Real-Time Consultation.** In addition to a dedicated point person, 60% of all participants acknowledged that the most successful support strategy in producing a high quality IRB application is having access to live, real-time IRB consultation. Participants cited numerous benefits of consultations, including receipt of project-specific considerations, personalized attention, useful takeaways, and practical point of performance education. Real-time consultation is the most successful in producing quality IRB applications because it bypasses the problematic aspects of overbroad training and information-dense websites, policies, and manuals. It is a direct, one-on-one educative experience specific to the researcher, their research questions, populations of study, and study procedures. Drawbacks to this strategy are similar to assigning dedicated point persons: it requires infrastructure, appropriate staffing and job design, and can be challenging to offer at scale.

**Providing a Rationale, or "The Why."** As noted in the literature review, a central criticism of IRBs is their lack of transparency, failure to clearly explain the rationale behind their requests, and limited inclination to communicate their decision-making. A handful of participants from both cohorts specified that one beneficial strategy the IRB can practice is to ensure the IRB's rationale, or The Why, is included in their application review exchanges. MGB Researchers reasoned that making the connection between the IRB's requests, and why they are being made and why they are important, is essential in contextualizing the request and recognizing its downstream impact on participants.

> "One thing that's really hard is that [researchers] need to know more of a rationale about why things are being done, because that helps us to put it into context a little bit more." – Researcher, Participant 8

> "I've always worked an educational angle into my IRB correspondence because that's what I can do as an administrator. It's not putting it off on some other department or some program or some managers. This is what I can do to contribute to education - I write it right into my [IRB application review] comments." – IRB Professional, Participant 6

**An Exemplar Library.** Participants in both cohorts recognized that an Exemplar Library of quality IRB applications could be both a successful resource, as well as a bridge to application quality. Exemplars simultaneously provide researchers with direct access to high quality IRB applications and affirm the level of quality sought by the IRB.

Participants observed that other benefits of exemplars are that they help level set expectations, provide a head start and reduces lost time/reinventing the wheel, and can provide researchers with language they know is IRB approval-ready. In fact, 3 researchers interviewed

(27%) described how their labs already centrally store and share exemplary IRB applications with one another and how beneficial that sharing is. Unfortunately, these researchers also revealed using their lab's exemplar repositories a resource when the IRB is unresponsive, or to bypass engaging with the IRB at all. There is nothing inherently wrong with this practice however when such resources are known to be helpful, and researchers are creating them on their own, it suggests a partnership opportunity that the IRB should seize.

**Other Successful Strategies.** In addition to the four primary strategies identified above, participants provided a handful of other strategies that did not saturate the responses, but that I personally find to be intriguing and potentially very useful. These suggestions included inviting researchers to be IRB members, creating a one-page quick start guide, developing a voluntary internal audit service, and producing a list of common pre-approval application pitfalls and post-approval audit triggers. Finally, hiring a capable research assistant is another strategy for support but the availability of this resource varies widely across researchers, their labs, and institutions. As noted, staffing and resources are a large barrier to IRB application quality and downstream impacts of inadequate staffing and resources may unmask limited research oversight and non-compliance.

## Recommendations

Introducing new ideas and concepts in organizations requires change management, socialization, and sensemaking. One benefit to a project like this - that studies a relatively under-researched topic - is that all learning can be new learning. Appreciating what was previously unknown can encourage new ways of thinking, invigorate individuals, spark creativity, and build momentum.

Lewin's landmark change management theory (1947) simplifies his theory of change management in three-stages: unfreeze, change, and freeze. In other words, his theory recommends organizational diagnosing of problems, interventions for change, establishing ownership and support, and then integrating sustainable strategies over time. I believe this project has completed all but the final step in this process, and hope the recommendations listed below provide a credible basis for evidence-based decision making at MGB and beyond.

### *Recommendation 1 – Establish an Internal Evaluation Process.*

American management expert W. Edwards Deming famously stated: "Every system is perfectly designed to get the results it gets" (Deming, n.d., line 1). Organizations have a responsibility to design their systems in a way that produces the results they seek. IRBs are no different. Findings from this study establish that MGB IRB Professionals recognize quality is an inside job, and they are aware that their processes could be designed to achieve better IRB application quality. For example, removing regulatory jargon from the application or making enhancements to the MGB IRB application system, Insight.

Establishing a formal internal evaluation process can benefit an organization's entire human research protection program (not just the IRB application itself), and attend to the IRB's goals of compliance, efficiency, effectiveness, and other targeted metrics. A range of IRB standards could benefit from periodic, intentional review including, but not limited to, templates and forms, policies and procedures, member composition, staff performance reviews, emergency

preparedness plans, participant outreach, communication methods, and resources such budgeting, staffing, and space.

Additionally, education and training offerings should also be scrutinized as part of an internal evaluation. IRBs that reflect on their educational offerings and utilization will be better positioned to fulfill the needs of their research communities. There is also a clear need to dedicate time to fully review all digital and technological IRB resources, e.g., reconciling broken links and outdated content, as well as reducing clicks and time spent searching online for answers. Finally, conducting a root cause analysis of communication bottlenecks and IRB staff responsivity is also critically needed. Without such interventions, researchers will continue to find workarounds, such as submitting the application as-is to see if it's acceptable.

Performing a fixed review of the entire IRB application is, at minimum, essential at an annual cadence. Rousseau (2018) recommends that organizations conduct periodic after action reviews (AARs) for iterative process improvements. AARs can

> "revisit a recent set of decisions in order to evaluate their effectiveness, helping decision makers reflect on the processes they used, assumptions made, and the implications for future decisions. Four questions are asked: (1) What did we set out to do? (2) What actually happened? (3) Why did it happen? (4) What are we going to do next time?" (pp. 9-10).

An AAR can help IRBs confront past practices, reflect on current norms, awaken new ideas, drive strategic decision-making, and improve operations. This includes scrutinizing resources, educational materials, methods, and the user experience. As this project shows, a one-size-fits-all approach to the IRB experience is not effective; improvements and positive change are a result of committed, ongoing, iterative efforts. Systematizing an internal evaluation demonstrates the IRB's commitment to process improvements, particularly those that lead to quality IRB applications. Developing standard operating procedures (SOPs) can also increase transparency by describing how the IRB will evaluate its resources, when the periodicity of review will occur, and what deliverables will be generated as a result of the evaluation.

One strategy is to form a working group of stakeholders (IRB staff, researchers, senior leaders) to involve the research community in annual evaluations of the IRB, solicit their feedback, and act upon their suggestions. This can be a collaborative and productive way of validating collective input, and creating a community of advocates who can champion this work.

***Recommendation 2 – Support a Start-to-Finish Framework.***

There are two elements to navigating the IRB experience – 1) broadly understanding research methodology, sound science, and the ethical treatment of human subjects *and* 2) submitting an approvable IRB application. The unsuccessful training strategies identified throughout this project unmask where barriers occur, and why traditional training and successful learning diverges. IRB education typically focuses on the broad conduct of research, and yet IRBs expect the result of training is a quality IRB application. These are the two important and necessary pieces of the responsible conduct of research, but they individually serve different ends and it is problematic to conflate the two.

> “Policy is different from example. The policies how we do the IRB [application] are important, but like there's a difference between reading like 30 pages of the policy and this is what we expect the product to look like are different.” - Researcher, Participant 14

> “[One thing] I do think is actually super important and gets lost sometimes is including what actually is happening at our site. You can get a very detailed, good protocol from a sponsor and actually have no clue about what it means at your site...I feel like there's two separate questions: one is what is a quality IRB application and then what is a quality protocol.” – IRB Professional, Participant 3

Relative to determinants of quality, the IRB has no way to change a researcher’s level of experience but they do have significant control over helping researchers compose a thorough IRB application. As reported above, a comprehensive start-to-finish accounting of the entire study forecasts the quality of an IRB application. I recommend incorporating such a framework into the IRB application itself to pinpoint the rigor the IRB seeks and to remove any guesswork for researchers.

A quality-promoting, start-to-finish framework can be established by the IRB in several ways. First, the IRB application can be intentionally structured with a start-to-finish flow of questions. This provides guardrails identifying the level of detail the IRB expects and increases sensemaking within the application. Second, the IRB can label its training materials as being policy-focused or procedure-focused. Clearly delineating these differences for the research community allows for easier navigation of IRB resources. Third, the IRB can create a workflow start-to-finish framework checklist so researchers can arrange each piece before starting their IRB application. Concurrent with the recommendation to establish internal evaluations, periodic evaluation of this framework is another way the IRB can promote IRB application quality without relying on researcher experience alone.

***Recommendation 3 – Enhance the User-Friendliness of the IRB Experience.***

Internal evaluation and a guiding framework can strengthen the IRB application, but the experience itself also requires review. To that end, the IRB should consider enhancing the user-friendliness of the IRB application experience and involve their research community in doing so. For example, MGB Researchers voiced concern about being unclear on where their IRB application is in the review workflow/process at any given time. This can cause frustration as researchers are not sure if they are days, weeks, or months away from IRB approval. One way to increase review-status transparency may be to update the Insight system to send an automated status email, enhance with a workflow progression bar, or develop an at-a-glance project status feature on screen. Walking through Insight with an end-user/researcher could shed light on user-facing parts of the system that IRB staff do not use and thus would not know are barriers to IRB application quality.

***Recommendation 4 – Introduce Point of Performance Training.***

General IRB training will remain useful in certain circumstances, such as orienting a new research coordinator. The IRB should continue to offer general or basics training for those audiences that benefit from them however, before proceeding, an assessment of utilization should be conducted to confirm *who* is benefitting from these trainings and *why* (i.e. invoke Lewin's concept of freeze and diagnose before assuming general training is effective).

Overwhelmingly MGB Researchers and IRB Professionals agreed that upstream, direct dialogue, project-specific consultation and human help were the most successful education strategies when it comes to producing a quality IRB application. Based on these preferences, there is strong evidence to support shifting away from general training and towards Point of Performance training instead. I define Point of Performance training as having two components:

1. The temporal component of training readiness; point of performance training occurs at the time the researcher is ready to prepare their IRB application and
2. the substantive component of the training itself which is need-based, i.e. IRB professionals must meet researchers where they are in terms of their individual needs, experience, time, and resources.

Researchers are actively and practically ready to receive IRB training at the point of performance (i.e. when they are ready to submit their project's IRB application). It is at this inflection point that they are ready, willing, and motivated to successfully navigate the application process and submit a quality application. Any time point prior to the point of performance will be an abstract thought exercise – which is why traditional IRB training is unsuccessful and why experience is a determinant of application quality. The IRB application process is an experiential one. Much like learning to ride a bike – you can't acquire that skill by reading about it in a book; you need to be on the bike and ready to ride.

As noted in the literature review, experiential education models provide a promising set of tools for IRB professionals to use while supporting researchers that face authentic, real-world knowledge gaps. This includes giving researchers feedback on their knowledge gaps, evaluating how researchers activate prior knowledge, recognizing researchers' motivation to learn, and providing instruction that will precisely target the gap (Huang & Hung, 2018; Loibl et al., 2017). Point of performance training can be designed and executed in multiple ways, depending on the prior experience of the researcher and their individual needs. For example, researchers may want to meet one-on-one with an IRB staff member, they may want to watch a video that can start and stop as they complete the application, others may want to compose a draft application and then call a dedicated point person when they get stuck, and some want to delegate to their more-than-capable researcher coordinators.

The conceptual frameworks of experiential and transformative education indicate that the pedagogical approach can be profound because it firmly roots learning in "the dynamic present" – at the point of performance. Experiential and transformative education theorists call upon educators (in this case, the IRB) to co-construct learning environments that are built on joint communication, critical intervention, knowledge creation, and sensemaking. Each of these components occur naturally in practice when IRB professionals and researchers engage in one-on-one consultation. By co-constructing the learning environment in real-time, at the point of performance, IRB professionals and researchers engage in modeling and mastery within the researcher's own application and produce lasting lessons that can be repeated in future applications.

The following quote articulates why Point of Performance training can promote IRB application quality when compared to traditional pedagogical approaches by the IRB:

> “The idea of [a researcher] really having a vested interest in something; they're not going to learn until they are really ready to learn, [until] it's really going to benefit or move forward what they're doing. The idea [of] putting a training out there and [assuming] they'll take this training and it could apply to a project to the future. [Instead], I think [training] really needs to be [at the] point of performance; when you're ready to use it.” – IRB Professional, Participant 4

***Recommendation 5 – Appoint a Dedicated IRB Point Person.***

Over 70% of MGB Researchers indicated that having a dedicated IRB point person would be the most successful support strategy *and* most impactful bridge to IRB application quality. That said, this recommendation would also represent the biggest sea change for MGB. Because this recommendation would require significant rearrangement of current operations, it merits deliberate consideration and further study relative to MGB’s needs. In a word, this recommendation may be an aspirational one at this point.

If this recommendation were pursued, one way to equip IRB staff with the requisite expertise to implement this model would be to employ job design strategies like requiring the Certified IRB Professional (CIP) credential, cross-functional training, or delineate IRB staff positions between junior and senior review specialists based on years of experience.

***Recommendation 6 – Supply “The Why.”***

The IRB typically has no trouble articulating clarifications or requests from researchers, but can fall short when supplying the reason the request is necessary, required, or important. The regulations require IRBs to document the basis for requested changes in IRB meeting minutes (HHS, 2019, 45 CFR 46.115(a)(2)). However, the IRB can be inconsistent in doing so because the loophole is that not every IRB application is reviewed at a convened meeting where minutes are recorded.

At its core, IRB review that includes a clear request/rationale structure is an exercise in sensemaking. According to Weick (1993) “the basic idea of sensemaking is that reality is an ongoing accomplishment that emerges from efforts to create order and make retrospective sense from what occurs” (p. 635). This specific kind of sensemaking can reinforce experiential and transformational learning theory frameworks by establishing a shared goal between IRB and researcher, providing models of success through personalized feedback, and creating opportunities for researcher's mastery and reflection. Ultimately sensemaking as a pedagogical tool in the IRB context can emphasize the researcher's role in their own learning about how to address the IRB's current concerns and how to apply that learning to the next application. This compliments the finding that experience is a determinant of application quality; researchers who have been through this process have acquired this level of sensemaking and can then repeatedly apply that learning.

The literature on this topic is clear: vague and uninstructive IRB review perpetuates the impression that IRBs are arbitrary and refuse to communicate their decision-making. As such, IRBs must end these vague practices, whether intentional or unintentional. Providing a clear

explanation and rationale for each request promotes IRB application quality, provides support, and increases sensemaking. Most important, providing a rationale is a method of education. Often we don't think of it that way, but the formal exchange of requests and reasons for those requests during IRB review is a powerful pedagogical tool.

> “I've always worked an educational angle into my IRB correspondence because that's what I can do as an administrator. It's not putting it off on some other department or some program or some managers. This is what I can do to contribute to education - I write it right into my [IRB application review] comments.” – IRB Professional, Participant 6

***Recommendation 7 – Create an Exemplar Library.***

The IRB should consider co-curating an Exemplar Library with their research community. IRBs can reach out to researchers/labs that consistently produce quality IRB applications and ask for their permission to use their work (redacted as needed). Exemplars could be organized singularly by application section or topic (study design, consent process, data confidentiality, HIPAA compliance, recruitment language) or could be broadly organized by project, population, or research question.

In line with providing “The Why,” presenting exemplars in isolation may fall short without a description of *why* it is exemplary. The IRB should provide details on why the exemplar was chosen and possibly go further and offer that an IRB staff member is available to review exemplars with researchers as needed.

## Conclusions

### MGB as a Model for Other IRBs

It is clear MGB IRB Professionals recognize how instrumental they can be in improving IRB application quality. During the interviews, they consistently reflected on personal ownership as an integral part of providing the most successful and helpful support possible to the MGB research community. This is truly a shining example for other IRB professionals, and indicative of a thoughtful staff who are committed to their work. Over 50% of MGB IRB Professionals acknowledged that their contributions and ownership of improvements can directly impact researchers in better ways. However, limited staffing and resources within the MGB IRB prevent the fulfillment of such admirable goals. This is not uncommon in academic and clinical settings with active research communities; many IRBs struggle with the resources to provide researchers with the attention they need and expect. MGB is just one example of how even large, resourced IRBs need help in scaling up much needed front-line services.

Additionally, IRB professionals likely have not been formally trained to innovate new pedagogical approaches in human subjects protections education, so they rely on traditional models without a path forward. It is clear external pedagogic consultation is useful to scope such problems directly with key stakeholders (i.e., both researchers and IRB professionals).

The level of engagement demonstrated by MGB IRB Professionals is a promising forecast of how welcome change management efforts would be at MGB, as well as at any IRB where the staff exhibit the same level of earnest interest and curiosity in improvement.

The following quote calls attention to the fact that there is much work to do in this area, but that such efforts can accomplish the goal of increasing in IRB application quality.

> "The more specific our Insight [online IRB submission platform] and Detailed Protocol template instructions are for Investigators and Study Staff, the better quality of incoming submissions we receive at intake/triage. It's directly proportionate. It is critical the IRB is clear and direct in what we are asking investigators to submit to us at the onset, so that they understand exactly what information we need in order to conduct a thorough yet efficient review. From my vantage point, I have seen time and time again confusion coming from the research community because the IRB instructions have been inadequate or missing completely. We've made significant improvements in this area over the past few years, and I've noticed complaints and questions from the research community decrease. I believe that continued improvement of our Insight and template instructions (such as providing a rationale for why the IRB is requesting certain information) will contribute to an overall increased quality of incoming submissions." – IRB Professional, Participant 20

**Limitations**

Limitations of this project include the small sample size and MGB-specific study setting. Based on these two limitations, there could also be some questions on the overall generalizability of my findings. Another limitation is my own potential and native biases and assumptions acquired over my 15+ year IRB and research administration career.

One limitation specific to MGB is an inherent biomedical focus of the research conducted at their hospitals. Future studies could look at similarities and differences of social-behavioral research vs. biomedical research application quality. Another MGB-specific limitation is that the inclusion criteria for the researcher cohort required recent receipt of IRB approval. Therefore, these participants would have had prior experience. Further areas of study may be to intentionally target inexperienced or new researchers. It could be interesting to cross-compare their impressions/perspectives on quality to researchers with IRB application experience.

Finally, a broad limitation is that there is a distinction between an Institutional Review Board (IRB) and a human research protection program (HRPP) that could impact this work. An HRPP is a collaboration between all organizational stakeholders involved in human subjects research and protection, including institutional leaders and policyholders, ancillary reviewers, legal counsel, quality improvement/auditing programs, researchers, *and* the IRB. The IRB itself is the committee that reviews and approves human subjects research, but operates under the auspices of the entire HRPP. This project did not make this distinction for participants, as IRB application review is handled primarily between the IRB and researcher. Gathering perspectives from an entire HRPP on application quality was out of scope for this project however, it may be informative to gather insights from all HRPP stakeholders in future iterations of this work.

**Conclusion**

Sociologist William Bruce Cameron wrote: "Not everything that can be counted counts, and not everything that counts can be counted" (1963, p. 13). This is the tension between

downstream effects and upstream solutions for a problem of practice like IRB application quality. The downstream impacts of a poor quality IRB application are evident, serious, and potentially innumerable. Upstream impacts are largely invisible and can thus seem less urgent. However, characterizing quality *is* urgent. Without it, two consequences are guaranteed: 1) IRBs will continue reacting to downstream problems resulting from poor quality rather than proactively seek mitigation upstream and 2) researchers will continue to perceive the IRB as obstructive, regard their interactions as negative, and find the application process confusing.

For too long, issues of quality and education have been insufficiently researched by the IRB community. As noted in the literature review, Pech et al.'s work (2007) provides the closest approximation that exists in the literature, aiming to "provide practical guidance that can minimize the difficulties researchers sometimes encounter during the IRB review and approval process" (p. 618). The unique benefit of this project, and my personal experience, is that it combines my doctoral training and career in research administration to break new ground in this area. In doing so, I have advanced the inaugural work of Avci (2017), Pech et al. (2007), and Sieber & Baluyot (1992) by explicitly characterizing the concept of "quality" IRB application. Additionally, I have furthered the existing scholarship by offering a pedagogical approach that researchers endorse as the most successful for them (i.e. point of performance training).

Together with characterizing quality, this project explored how the IRB application review process can be educative, provide researchers with practical tools to produce quality IRB applications in real time, and increase application quality over time. Key findings of this project led to the development of a roadmap that supports and enhances IRB application quality.

IRBs have consistently innovated flexible and creative approaches to their work where the regulations are noticeably silent. Appeals for a definition of IRB application quality, and how to achieve it, have been continuous and IRBs cannot afford further delay. IRBs can use findings from this project as standards of evidence to establish measurable metrics on quality, and to focus their efforts on education that will actually facilitate quality IRB application preparation. In doing so, IRBs are better positioned to assess the regulatory, ethical, scientific, and administrative requirements of a proposed human subjects research study, strengthen the research-practice nexus at their organization, and ultimately enhance the protection of human subjects.

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# Appendix A

## List of Mass General Brigham HRPP Covered Entities

The Mass General Brigham (MGB) HRPP is an integrated program with overall responsibility for the protection of the rights and welfare of human subjects in research for MGB. The entities owned by, and covered under the Mass General Brigham HRPP (HRPP Covered Entities), include:

1. The Brigham and Women's Hospital, Inc. (BWH)
2. Brigham and Women's Faulkner Hospital, Inc. (BWH/F)
3. Massachusetts General Hospital (MGH)
4. The MGH Institute of Health Professions, Inc. (MGH IHP)
5. The McLean Hospital Corporation (McLean)
6. Newton-Wellesley Hospital (NWH)
7. North Shore Medical Center, Inc. (NSMC)
8. Massachusetts Eye and Ear Infirmary (MEE)
9. Partners Private Care, LLC (PPC)
10. Partners Home Care, Inc. (PHC)
11. The Schepens Eye Research Institute, Inc. (SERI)
12. The Spaulding Rehabilitation Hospital Corporation (SRH)
13. Spaulding Hospital for Continuing Medical Care Cambridge (Spaulding Cambridge)
14. Spaulding Hospital of the Cape and Islands Corporation (Spaulding Cape Cod)

Appendix B

Interview Guides by Participant Group

**Interview Guide for Group 1 – MGB IRB Professionals**

1. Describe your role within the MGB IRB, including any specialized areas of expertise and years in this position.

2. In general, what are the goals of what the IRB does? List as many as you can think of.

3. How do you define or characterize a "quality" biomedical IRB application? Describe both a high-quality and low-quality application.

4. In your experience, what is the biggest determinant of the quality of a biomedical IRB application? *(prompt if needed: PI experience, study design type, research topic, sample population, research activities)*
    a. Is researchers' [regulatory, ethical, scientific, administrative] knowledge a factor?

5. What are the most important things a researcher can do to prepare a quality IRB application?

6. How does the MGB IRB support and/or assist researchers in producing quality IRB applications?

7. In your opinion, what IRB-related education/training strategies are the most successful? Which haven't worked?

8. What do you think are the barriers to producing a quality IRB application?

9. What impact do you think the quality of the IRB application has on the quality of IRB review provided?

10. What are your thoughts on the IRB approving applications that are "good enough" versus "as good as possible"? *(prompt if needed: low-risk but poorly designed or without substantial rigor vs. iterating until its perfect just to find out it's no longer feasible to conduct, too laborious, or wastes resources)*

11. Do you think the merit of a study impacts the quality of the IRB application? If yes, how/why? *(prompt if needed: merit = individual, social, scientific value)*

12. Are there obvious connections between study teams that need post-approval monitoring or have noncompliance and the quality of their IRB applications?
    a. Similarities between "repeat offenders" or frequent fliers?

13. What would you recommend to promote and enhance the quality of an IRB application?

14. Is there anything else you would like to share that we haven't covered?

**Interview Guide for Group 2 - MGB Researchers**

1. Describe what kinds of research you typically conduct, your areas of expertise, typical role as a researcher, and years conducting human subjects research.

2. In general, what are the goals of what the IRB does? List as many as you can think of.

3. How do you define or characterize a quality IRB application?

4. What do you think are the barriers to producing a quality IRB application?

5. In your opinion, what is the biggest determinant of the quality of a biomedical IRB application? *(prompt if needed: PI experience, study design type, research topic, sample population, research activities)*
    a. Is [regulatory, ethical, scientific, administrative] knowledge a factor?

6. Do you think the merit of a study impacts the quality of the IRB application? If yes, how/why? *(prompt only if needed: merit = individual, social, scientific value)*

7. Have you ever had an IRB application disapproved? What happened? // Tell me about a time when you had an IRB application that was approved and what went right.

8. I want you to think about a time when the IRB requested additional information from you. Did you have that information at hand or did the request take you completely by surprise? If at hand, why wasn't it initially included?

9. What specific supports do you have in place when you go through the IRB application process? *(prompt only if needed: dedicated study coordinator, IRB staff liaison, delegated help preparing application, submission assistance service, etc)*

10. How does the MGB IRB support and/or assist researchers in producing quality IRB applications?

11. In your opinion, what IRB-related education/training strategies are the most successful? Which haven't worked?

12. What impact do you think the quality of the IRB application has on the quality of IRB review provided?

13. What would you recommend to promote and enhance the quality of an IRB application?

14. Is there anything else you would like to share that we haven't covered?

# Appendix C

## Qualitative Codebook

| CODE BOOK | Frequency |
|---|---|
| Basic Goals of the IRB | |
| Participant protections | 11 |
| Facilitate research | 4 |
| Regulatory compliance | 7 |
| Follow ethical standards | 10 |
| Risk/benefit assessment | 7 |
| Ensure participant comprehension | 1 |
| Equitable subject selection | 2 |
| Institutional protection | 1 |
| Review the science | 3 |
| Help/assist researchers | 3 |
| Education | 1 |
| Relationship Between IRB & Researchers | |
| Revisions to previously approved study document | 2 |
| New regs vs. reviewer preference | 2 |
| Working collaboratively helps | 6 |
| Consult/conversation to avoid lengthy back and forth | 3 |
| Anonymity-transparency of the IRB is a barrier | 3 |
| Culture change-direct assistance | 1 |
| Human approach to interacting | 4 |
| Feedback loops & process improvement implications | 1 |
| The 4 Factors-Regs, Ethics, Science, Admin | |
| Importance of reg knowledge | 4 |
| Researchers lack reg knowledge | 3 |
| IRB lacks scientific knowledge | 5 |
| IRB basics knowledge impacts app quality | 5 |
| Admin/procedural knowledge impacts quality | 8 |
| Deferential to the IRB for their expertise | 4 |
| Researchers know science best | 2 |
| Regulatory language should be reworded/written in lay language | 7 |
| Scientific justification is critical | 4 |
| Combine all - it's a skill/art | 7 |
| Impact on IRB Review Quality | |
| Confidence check-red flags of bigger issues | 8 |
| IRB review will be good because that's their job | 3 |
| Sloppy-thrown together is frustrating | 4 |
| Thoughtful, attentive response goes a long way | 1 |
| Flags a closer look/review | 5 |
| Garbage in garbage out | 12 |
| Misunderstandings lead to miscommunication & nitpicking | 5 |
| More detail is better | 12 |
| Submit and see what happens | 7 |
| Problems at initial review proliferate if not addressed | 2 |
| No impact | 1 |
| Support, Training, Education | |

| Legend |
|---|
| 1st level code |
| 2nd level code |
| 3rd level code |

| | |
|---|---|
| Researcher's Support | 6 |
| MGB Specific | 9 |
| Unsuccessful Strategies | |
| Poor communication | 3 |
| Lack of IRB response-getting human help | 15 |
| CITI | 4 |
| Overbroad-general training | 15 |
| Information hard to find-website difficult to navigate | 14 |
| General IRB email address | 6 |
| Circuitous links-many broken | 6 |
| When process feels like paper pushing-admin burden | 2 |
| Doing nothing | 1 |
| Not applying prior application experience to future apps | 3 |
| Successful Strategies | |
| IRB rationale-the Why | 10 |
| Succinct communication | 4 |
| Exemplars-models | 12 |
| Live-real time-consultation | 25 |
| Dedicated IRB point person | 12 |
| Helpful colleagues-peers | 7 |
| Quick start guide-getting started fast facts | 3 |
| Trainings-webinars-orientations | 12 |
| More dialogue-clearer instructions | 10 |
| Having capable research assistants-coordinators | 9 |
| Institutional level support | 3 |
| Voluntary internal audits | 2 |
| Dedicated application prep request-intake form | 1 |
| Being an IRB member | 2 |
| Connecting with IRB before submitting | 3 |
| Mandatory training | 4 |
| Personal ownership | 8 |
| List of common pitfalls or common audit triggers | 1 |
| Supporting & Enhancing Quality (Roadmap) - App Process | |
| Missing Information-Had on hand | 7 |
| ID Barriers to Quality | |
| Resources-Staffing | 16 |
| Administrative hold ups-admin burden | 19 |
| Revised Common Rule didn't reduce burden | 1 |
| CRs are a waste of time | 1 |
| Requirement but doesn't protect HS | 3 |
| Availability of direct IRB help-assistance | 4 |
| Usefulness of IRB assistance (expertise) | 6 |
| Mismatch of details provided to IRB from researcher | 7 |
| Mismatch of expectations between IRB & researcher | 14 |
| Experience-familiarity with IRB/process | 22 |
| Difficulties using website-Insight | 13 |
| Having all pieces of IRB application available, easy to find | 10 |
| Repackaging grant to IRB app | 4 |
| Time | 15 |
| IRB staff bandwidth | 6 |
| Design-content of appmaterials-freq of changes | 26 |

| | |
|---|---|
| Overdelegating to research staff | 9 |
| IRB consistency | 2 |
| Cooperation | 7 |
| ID Bridges to Quality | |
| Transparency-timeline-who is reviewing and why | 7 |
| Experience-savviness | 11 |
| Connecting with IRB before submitting | 10 |
| Real time assistance | 5 |
| Adequate IRB expertise | 4 |
| Pay IRB members | 1 |
| Customized application package | 1 |
| Dedicated IRB point person | 12 |
| Pre-screening-triage process | 4 |
| Complete as possible list of pre-review questions | 5 |
| Faster review | 4 |
| Template repository with clear instructions | 12 |
| Characterization of Quality | |
| Impact of Scientific-Social Merit | 14 |
| Biggest Determinant | |
| Clarity-well written | 3 |
| Scientific validity | 2 |
| Understanding of study start to finish | 13 |
| No one thing; combination of pieces | 1 |
| Experience | 4 |
| Time spent | 2 |
| POOR QUALITY | |
| App lacks details IRB needs-Incomplete | 22 |
| Obvious copy and paste | 2 |
| Sloppy-poorly organized | 11 |
| Appreciation for both sides of the process | 1 |
| Experience-not knowing what you're doing | 19 |
| Obviously no proofreading/oversight-direct PI involvement | 8 |
| Overly complex-too much crammed into one app | 2 |
| Lack of resources & training | 5 |
| Inconsistencies | 5 |
| Responsiveness | 3 |
| Starting from scratch-creating study docs yourself | 2 |
| GOOD QUALITY | |
| Organized | 5 |
| Well-written | 14 |
| Attention to detail | 16 |
| Clear demonstration of effort | 13 |
| Complete | 11 |
| Good science-clear purpose | 4 |
| MGB IRB Operations | |
| Internal Assessment | 22 |
| Forms & Templates | 26 |
| INSIGHT System | |
| Cons | 27 |
| Pros | 1 |
| GOOD QUOTE | 31 |