Performance Measures for Institutional Review Boards

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THESIS
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This dissertation is dedicated to my dear late mother, Maryla Paluta and my father, Jerzy Paluta.
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SUMMARY

This dissertation is comprised of two papers that explored performance measures for institutional review boards. The first paper is a literature review of advisory, regulatory, accreditation, and empirical literature focused on IRB performance. The literature review examined historical efforts to evaluate IRBs since their inception, and confirmed that empirically based definitions of IRB performance and mechanisms to systematically evaluate IRB performance are limited.

The second paper is an exploratory descriptive study exploring IRB quality measures. The study examined the processes that IRB members used to complete protocol reviews, characteristics of a quality protocol review, and IRB member role in human subject protection. The study also explored IRB members’ perspectives and recommendations for IRB quality measures. The study identified tools facilitating protocol reviews and challenges that IRB members reported regarding protocol review completion. The study’s finding regarding differences in evaluative methods and steps used by IRB members to review protocols made a unique contribution to existing literature on IRB performance. The study’s other unique and important contribution was the exploration of IRB quality measures from the perspective of IRB members. IRB members described quality measures that focused on enhancement of human subject protection, relationships with investigators, and IRB member education, mentoring, and peer review. The study offered a beginning framework for the development of IRB quality measures.
I. INTRODUCTION

This dissertation is comprised of two manuscripts that explore IRB performance. The first manuscript reviews key published advisory, regulatory, accreditation, and empirical literature focused on IRB performance. The literature review provides a historical account of efforts made to evaluate IRBs since their inception and identifies the paucity of empirically based definitions of IRB performance and mechanisms to systematically evaluate IRB performance. The literature review confirms that research examining the quality of IRB oversight of human subject protection is limited.

The second manuscript is an exploratory descriptive study exploring IRB quality measures. The study examines the processes by which IRB members completed protocol reviews, explored features of a quality protocol review and their role in human subject protection, and reflected on their thoughts and recommendations for IRB quality measures. The study identifies tools facilitating protocol reviews and challenges that the IRB members reported regarding completion of protocol reviews. The study’s identification of differences in evaluative methods and steps used by IRB members to review protocols make a unique contribution to the existing literature on IRB performance. The study’s other unique and significant contribution on IRB performance is the exploration of IRB quality measures from the perspective of IRB members. IRB members described quality measures that focus on enhancement of human subject protection, relationships with investigators, and IRB member education, mentoring, and peer review.
II. QUALITY MEASURES FOR INSTITUTIONAL REVIEW BOARDS:

WHAT THE LITERATURE SHOWS

A. **Introduction**

Institutional review boards (IRBs) use codes of ethics, federal regulations, and accreditation standards to evaluate, monitor, and oversee risks posed to human subjects. Little is known about the adequacy of this evaluation, monitoring, and oversight due to a lack of objective, measurable quality indicators and outcome measures for IRBs (U.S. Department of Health & Human Services, 2006). Since the establishment of IRBs 35 years ago, published advisory recommendations and regulatory findings have identified the need to evaluate IRB oversight of human subject protection. Studies have explored IRB membership, IRB structure, variability in review processes, outcomes, operating costs, and conflict of interest, but research evaluating IRB performance and effectiveness in human subject protection is limited (Abbott & Grady, 2011). Accreditation metrics for human subject protection programs identified high-performing practices for IRBs, but have not been empirically tested (Association for the Accreditation of Human Research Protection Programs, 2011). To date, the findings, studies, and metrics confirm that limited mechanisms are in place to systematically evaluate the quality of IRB oversight of human subject protection.

The purpose of this paper is to examine advisory, regulatory, accreditation, and empirical literature focused on IRB performance. Key published advisory and regulatory findings from Presidential commissions, advisory committees, and the U.S. Department of Health and Human Services (DHHS) Services Offices of Inspector General (OIG) and Human Research Protection (OHRP) are examined. Accreditation of human subject protection programs is reviewed. Also
explored are empirical studies that explore (1) IRB and research ethics committee protocol review (REC) processes and deliberations and (2) IRB and REC relationships with investigators.

B. **Background**

1. **Advisory Recommendations and Regulatory Findings**

   Published advisory recommendations and regulatory findings identifying the need for improvement in IRB performance constitute the majority of IRB performance literature to date, and are summarized in Appendix A. Following publication of ethical guidelines for human subject protection by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research in 1979, the need for improvement in IRB performance was identified by the President’s Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research in 1983. The Commission identified inadequate institutional support for IRBs and insufficient education of investigators and IRB members regarding their roles and responsibilities in human subject protection; it also recommended the formation of an ethics advisory board for human subject protection (President’s Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, 1983).

   Inadequate IRB protection of human subjects was identified by the Advisory Committee on Human Radiation Experiments (ACHRE) in 1996. The Committee identified significant risks to human subjects, including a lack of human subjects’ understanding of the differences between research and standard clinical practice, inadequacy in the consenting process for human subjects with limited decision-making capacity, and inconsistency in IRB review processes (ACHRE, 1996). At the request of the Senate Committee on Governmental Affairs that same year, the U.S. General Accounting Office (GAO) issued a report supporting earlier findings of inadequacies in
IRB performance (GAO, 1996). The GAO reported a lack of IRB preparedness to review complex research resulting from limitations in IRB member scientific expertise, and it reported evidence of IRB member financial and personal conflicts of interest (GAO, 1996).

Ongoing inadequacies in IRB protection of human subjects resulted in multiple site inspections by the DHHS OIG in 1997. The OIG identified deficiencies in IRB performance and insufficient IRB adaptation to the growth of pharmaceutical and other industry-sponsored research (DHHS, 1997). A key finding in the OIG evaluation was the lack of any mechanism for IRBs to evaluate their effectiveness. The OIG found the following:

IRBs rarely conduct inquiries to determine how well they are accomplishing their mission; their judgments of effectiveness rely mainly on the number of protection lapses or complaints that are brought to their attention. The HHS agencies conducting oversight seldom go any further. The Office for Protection from Research Risks, in the National Institutes of Health, focuses almost entirely on upfront assurances. The Food and Drug Administration relies on compliance-focused inspections. (DHHS, 1997, p. iii).

The OIG recommended that IRBs be held more accountable for results, and that a mechanism be developed for IRB performance-focused reviews.

Formed in 1995 to serve as an ethics advisory board for human subject protection, the National Bioethics Advisory Commission (NBAC) published reports between 1995 and 2001 that supported the ACHRE, GAO, and OIG findings of inadequacies in human subject protection programs and IRB performance. The Commission confirmed the need for increased IRB oversight of research involving human biological materials and subjects with impairment in
decision-making abilities (NBAC, 1998, 1999). It recommended the development of education programs in research ethics and examination of issues unique to international human subject research (NBAC, 2001a, 2001b). The Commission also identified inadequate resources and overbearing regulatory procedural requirements impacting the work of IRBs (NBAC, 2001b).

The Office for Protection from Research Risks, National Institutes of Health (OPRR), began aggressive investigations of human subject rights violations and noncompliance in human subject protection programs in the late 1990s, resulting in well publicized IRB closures and suspension of federally funded research at institutions. The Office for Human Research Protections, Department of Health and Human Services (OHRP), was formed in 2000 to respond to IRB failures and ensure stronger federal regulatory oversight of human subject protection programs. OPRR and OHRP investigative findings of noncompliance in human subject protection programs were examined by Borror et al. (2003). Borror et al. (2003) analyzed 269 compliance oversight determination letters issued to 155 institutions by OPRR and OHRP between October 1, 1998, and June 20, 2002; these letters reflected noncompliance findings, as well as deficiencies in human subject protection programs for which institutions took corrective action. According to the authors, 27% of the citations were the result of noncompliance and deficiencies involving informed consent; these were the most common OHRP citation for that review period. The most frequent citations regarding informed consent included failure of the consent documents to describe the study purpose, procedures, and duration, and failure to provide adequate information related to study risk and discomforts.

Burris and Welsh (2007) reviewed 271 OHRP compliance oversight determination letters issued between January 1, 2002, and June 30, 2004 and five additional letters issued before the review period. The authors removed redundant letters that were the result of multicenter trials
and retained 155 letters: 29 letters resulting from OHRP compliance audits at 19 institutions and 126 letters resulting from 91 complaint investigations for analysis. After categorizing the problems identified in the OHRP audit and complaint letters, Burris and Welsh reported that inadequacy in the documentation and process of informed consent was the most frequently cited problem during that time period (Burris & Welsh, 2007). According to Burris and Welsh (2007), inadequacies in informed consent documentation included the use of language not understandable by the subject, absence of elements required by the *Common Rule*, and evidence of exculpatory language or otherwise asking the subject to relinquish rights to consent to study participation. The authors reported that the inadequacies in informed consent process included obtaining proxy consent in situations where asking the subject directly would have been appropriate, obtaining subject consent to study participation after the subject started in the study, not obtaining subject consent, and using undue influence or coercion to obtain subject consent.

A third analysis of OHRP compliance oversight letters was published by Weil et al. (2010). The authors reviewed 235 OHRP determination letters issued to 146 institutions between August 1, 2002, and August 31, 2007, and examined trends that had evolved since their 2003 publication. Weil et al. (2010) found that inadequacies in informed consent remained the most frequently OHRP-cited institutional deficiency. Additionally, the authors identified an increase in the percentage of institutions cited for noncompliance resulting from investigator-initiated changes to study protocols without prior IRB review and approval (Weil et al., 2010).

The OHRP Division of Compliance Oversight published summaries of their noncompliance findings in 2005 and 2009. Both summaries reported an almost identical number of noncompliance findings; the 2005 OHRP summary reported 53 noncompliance findings, and the 2009 OHRP summary reported 51 noncompliance findings. The nature of the
noncompliance findings was also similar: 42 of the 51 noncompliance findings in the 2009 OHRP summary had been identified in the 2005 OHRP summary of noncompliance findings. The noncompliance findings of the 2005 and 2009 OHRP summaries related to informed consent were analyzed in the Borror et al. (Borror, Carome, McNeilly, & Weil, 2003), Burris and Welsh (2007), and Weil et al. (2010) publications. Additionally, the OHRP 2005 and 2009 summary reports identified similar deficiencies in IRB membership expertise, staff, support, and workload that were identified in the 2001 NBAC findings, raising concerns about continuing inadequacies in IRB performance and human subject protection (NBAC, 2001b; DHHS, 2005, 2009).

Burris and Welsh (2007) also supported the NBAC 2001 findings of overbearing regulatory and procedural requirements for IRBs. They challenged OHRP for its reactive response to human subject right violations, and expressed concern that institutions were spending more resources to meet OHRP requirements and fewer resources to protect human subjects (Burris & Welsh, 2007). The authors recommended fundamental and urgent changes in federal regulations and oversight processes for human subject research. That same year, Taylor (2007) explored an ethical framework for evaluating IRB performance to ensure adequate IRB consideration of ethical guidelines for human subject protection. Acknowledging that components of ethical evaluation of proposed research were previously identified by others, Taylor recommended the integration of these components to develop measures for review of ethical quality of IRB oversight of human subject research. The components of ethical evaluation of proposed research summarized by Taylor included the following:

Scientific merit/value of the proposed research; identification and assessment of risk to subjects/society; identification and assessment of benefit to subjects/society; acceptable risk/benefit ratio; fair approach to the selection of subjects; adequate informed consent
process, including attention to potential barriers to understanding, threats to voluntariness; whether and how those with limited decision-making capacity should be included in the study; and adequate mechanisms for respect of enrolled subjects…

(Taylor, 2007, p. 10-11)

The author proposed the development of an ethics review instrument using these components to measure ethical quality of IRB protocol reviews (Taylor, 2007).

Human subject protection was examined by the Presidential Commission for the Study of Bioethical Issues in 2011. The Commission investigated the 2010 revelation of unethical research in Guatemala supported by the U.S. Public Health Service in the 1940s, and also evaluated existing regulations for human subject protection. The Commission confirmed that “the current U.S. system provides substantial protections for the health, rights and welfare of research subjects...” and “finds significant room for improvements…” (Presidential Commission for the Study of Bioethical Issues, 2011, p. 5). The Commission made a number of recommendations to improve human subject protection. Of significance to this IRB performance literature review was the Commission’s second of 14 recommendations identifying the need to evaluate the effectiveness of programs and regulations responsible for human subject protection and develop empirically based methods to assess the protection of human subjects.

That same year, DHHS issued an advance notice of proposed rulemaking (ANPRM) changes to the Common Rule to enhance human subject protection and increase effectiveness in the review of human subject research (DHHS, 2011). DHHS acknowledged the significant changes made in human subject research since the establishment of the Common Rule more than 30 years prior, including an increase in the number of multi-site studies, social and behavioral
studies, and use of technology. DHHS proposed changes to ensure human subjects were effectively protected in today’s research environment. Amendment of the Common Rule was also recommended by the 2011 Presidential Commission to increase accountability of investigators conducting human subject research (DHHS, 2011).

One proposed change in the 2011 DHHS APRNM related to IRB protocol reviews was the consideration of replacing prospective review of certain research presenting minimal risk with retrospective review. This proposed change would provide an investigator the opportunity to determine if a study meets appropriate criteria for minimal risk research, and conduct the study after notifying an IRB of the study. This proposed change would also provide an IRB the opportunity to conduct retrospective reviews of selected studies to confirm the investigator’s evaluation of the study as presenting minimal risk. Klitzman and Appelbaum (2012) suggested this proposed change could promote IRB review efficiency and support exploration of alternative IRB review processes.

2. Accreditation Efforts

The benefit of human subject protection program accreditation was first identified in advisory recommendations and regulatory findings. The 1983 President’s Commission report proposed an accreditation model using site visits and peer review to improve IRB performance and human subject protection. The 1996 GAO report and 1997 DHHS OIG findings recommended systematic evaluation of IRB performance to improve the quality of human subject protection. The Institute of Medicine (IOM) published recommendations in 2001 for the creation of accreditation standards for human subject protection programs. IOM examined draft accreditation standards, recommended pilot testing of proposed standards, and supported the use
of accreditation standards to improve the quality of human subject protection (IOM, 2001). The OHRP Secretary's Advisory Committee on Human Research Protections (SACHRP) Subcommittee on Accreditation supported the use of accreditation standards to evaluate IRB performance (DHHS, 2004).

Today, accredited domestic and international human subject protection programs receive their accreditation from the Association for the Accreditation of Human Research Protection Programs (AAHRPP). Formed in 2000, AAHRPP uses publicly available accreditation standards to evaluate human subject protection programs, including university-based and independent institutional review boards and programs based in academic medical centers, health care systems, laboratories, cancer treatment institutions, contract research organizations, and state health departments. The number of human subject protection programs accredited by AAHRPP has grown to approximately 200, and is expected to increase due to anticipated expansion of the research industry.

In 2011, AAHRPP published metrics on human subject protection program performance to promote high-performing practices for human subject protection programs (AAHRPP, 2011). AAHRPP used data from 193 accredited human subject protection programs to develop the metrics and provide a summary analysis of key practices in their accredited programs. AAHRPP 2011 metrics related to IRB performance focused on an organization’s use of its own IRB; use of external IRBs; number of IRBs; volume of IRB protocol reviews; IRB review times by type of review; IRB resources including member compensation, technology use, staffing, and funding levels; and volume of protocol deviations, complaints, and noncompliance. AAHRPP IRB metrics may provide institutions an opportunity to evaluate IRB workload and productivity and improve IRB functions.
Nevertheless, the metrics do not address IRB member peer review or any evaluation of the processes used by IRBs to make decisions. AAHRPP metrics for human subject protection programs may also provide institutions an opportunity to evaluate and improve their practices; however, the value of AAHRPP accreditation in improving human subject protection has not been empirically tested. Some continue to believe that AAHRPP is compliance-driven like OHRP. The Department of Veterans Affairs allowed its contract with AAHRPP for accreditation of its multiple human subject protection programs to expire in March 2012 and replaced it with services from Alion Science and Technology Corporation. Empirical testing of human subject protection program accreditation is needed to determine its effectiveness in improving IRB performance and human subject protection, and to identify differences in outcomes between accreditation organizations.

3. **Empirical Literature Evaluating IRB and Research Ethics Committee Performance**

Seven studies published in the last 10 years evaluating the performance of IRBs and a research ethics committee (REC) were reviewed and included six U.S. studies and one study conducted in Australia (Burris & Moss, 2006; Keith-Spiegel, Koocher, & Tabachnick, 2006; Reeser, Austin, Jaros, Mukesh, & McCarty., 2008; Feldman & Rebholz, 2009; Wisner et al., 2011; Guillemin, Gillam, Rosenthal, & Bolitho, 2012; Lidz et al., 2012a). The studies differed in sampling characteristics, sample size, and instruments measuring performance. In one study, Lidz et al. (2012a) evaluated the adherence of IRB protocol reviews to the *Common Rule* through observations, audio-recordings of IRB meetings at academic medical centers, and analysis of recorded protocol reviews. Four of the remaining six studies used surveys to evaluate IRB performance, including a national survey (Keith-Spiegel et al., 2006), institutional surveys
(Reeser et al., 2008; Feldman & Rebholz, 2009), and a professional organization survey (Wisner et al., 2011). In two of five studies using surveys, investigators were surveyed to evaluate IRB performance (Keith-Spiegel et al., 2006; Wisner et al., 2011). IRB members were also surveyed to evaluate their performance (Feldman & Rebholz, 2009). In a fifth study using surveys, investigators, IRB members, research coordinators, and research staff were surveyed to evaluate IRB performance (Reeser et al., 2008). Two remaining studies evaluated the performance of an IRB and REC through telephone interviews of investigators (Burris & Moss, 2006) and individual, face-to-face interviews with investigators and research ethics committee members (Guillemin et al., 2012).

The studies used different data collection methods and evaluated different aspects of IRB and REC performance. Lidz et al. (2012a) observed and audio-recorded IRB meetings at academic medical centers and transcribed, coded, and analyzed recorded protocol reviews to see what IRB members discussed and how well they addressed the Common Rule criteria in their discussion. The authors also reviewed the actual protocol applications presented at IRB meetings to evaluate how well the applications addressed the criteria outlined in the Common Rule and to determine how well the IRBs addressed the Common Rule when addressing each application. Feldman and Rebholz (2009) from Boston Medical Center developed a survey instrument to evaluate their IRB members’ meeting experiences. The authors examined members’ attitudes about efficiency, procedures, and outcomes of the meetings and asked members for recommendations to improve meetings. Wisner et al. (2011) modified a survey used previously to explore the impact of the HIPAA privacy rule on clinical research, and mailed the survey instrument electronically to members of the American College of Neuropsychopharmacology (ACNP) to learn about their experiences with IRBs. ACNP
members were asked about their experiences with single, multiple, and centralized IRB review processes and their perceptions of the impact of IRB review on their research efforts; members also were asked to recommend solutions for problems that resulted from IRB review of their research. Burris and Moss (2006) conducted qualitative interviews by telephone with investigators from throughout the United States to explore improvements needed for ethics review boards, and analyzed the recorded interviews for themes. Guillemin et al. (2012) interviewed REC members and researchers at the University of Melbourne, and analyzed the recorded and transcribed interview data using thematic analysis to understand committee members’ and researchers’ understanding and views of research ethics and ethic reviews. Keith-Spiegel et al. (2006) used a framework of organizational justice to develop a 45-item questionnaire known as the IRB Researcher Assessment Tool or IRB-RAT to rate the importance of IRB functions. The authors used the IRB-RAT to survey a large, national sample of investigators to explore what investigators wanted from their IRBs, and posted the assessment tools and a user guide on a public Web site to make the IRB-RAT available for use in future studies. Reeser et al. (2008) from the Marshfield Clinic Research Foundation in Wisconsin used the Keith-Spiegel et al. (2006) IRB-RAT two years later as a self-assessment tool and surveyed investigators, IRB members, research coordinators, and staff about IRB performance at their institution.

Although the studies differed in sampling characteristics, sample size, instruments, data collection methods, and features of performance, the study findings revealed two closely related themes influencing the evaluation of IRB and REC performance: IRB and REC protocol review processes and deliberations (Burris & Moss, 2006; Feldman & Rebholz, 2009; Wisner et al., 2011; Lidz et al., 2012a), and IRB and REC relationships with investigators (Keith-Spiegel et al.,
Lidz et al. (2012a) found that IRB members failed to consistently address all of the mandated criteria in the Common Rule while reviewing protocol applications. The authors used the following guideline to determine if a protocol review addressed the required Common Rule criteria: the IRB agreeing the protocol adequately addressed a criterion, the IRB raising questions for the investigator regarding the protocol, or the IRB recommending a modification of the protocol. According to Lidz et al. (2012a), the IRB made clear determinations on all relevant criteria for only 19% of protocols. The following criteria in the Common Rule were not addressed consistently by IRB members: risk minimization in 21% of protocols; risk/benefit ratio in 57% of protocols; equity in subject selection in 60% of protocols; data monitoring in 54% of protocols; privacy and confidentiality in 25% of protocols; and protection of vulnerable subjects in 13% of protocols. Informed consent was discussed 98% of the time, and questions about informed consent or recommendations for changes in informed consent were discussed for 88% of protocols. The authors identified the need for better reliability of IRB deliberations to ensure uniform application of the key seven criteria in the Common Rule. They also recommended that institutions revise their procedures and protocol review forms to monitor improvement of their IRB deliberations in applying the Common Rule. Feldman and Rebholz (2009) found that IRB members made constructive recommendations to enhance meeting efficiency and protocol review processes and outcomes by improving their deliberations (i.e., streamlining and abbreviating deliberations for repeated protocol submissions, taking responsibility for being familiar with previous board discussions about a protocol for repeated protocol submissions, and recognizing the significance in investigators attending IRB meetings to answer questions and clarify concerns). IRB chairs were provided survey results for presentation and discussion with their Board as part of a quality improvement effort. The
majority of ACNP investigators in the Wisner et al. (2011) study reported positive communication and interactions with their IRBs, and believed that IRB review improved their research protocols. However, some believed that IRB reviews were reactive and focused on issues not central to subject protection. They acknowledged delays in studies reviewed by multiple IRBs, and expressed concern that standards were not consistently applied by separate IRBs for multi-site studies. They also recommended that IRB members receive education focused on the consenting process for subjects with psychiatric illness due to concerns that IRB members were affected by the stigma of psychiatric illness similar to that experienced by the general public. The ANCP members’ feedback also focused on IRB protocol review processes and deliberations. Finally, the majority of investigators in the Burris and Moss (2006) study reported that they agreed about the goals of human subject regulations, but were skeptical whether ethics review committees promoted these goals in a facilitative way. Investigators raised issues about delays in studies reviewed by multiple IRBs, and expressed dissatisfaction with ethics review committee reviews of informed consent (Burris & Moss, 2006). Investigator feedback for ethics review committees in the Burris and Moss (2006) study focused on IRB protocol review processes and deliberations.

Guillemin et al. (2012) found that researchers and REC members agreed about the primary purpose of a REC in protecting human subjects. However, researchers experienced REC members as going beyond their stated role in protecting research subjects, and felt mistrust of REC members. Some researchers described REC members as paternalistic of research subjects, and believed that they overextended their stated role in requiring revisions of study methodology rather than advising researchers on study methodology. Researchers also expressed concern that REC members protected the institution’s interests. Guillemin et al.
(2012) expressed concerns that poor relationships between researchers and REC members had potential negative implications for human subject protection. Keith-Spiegel et al. (2006) found that investigators prioritized IRB characteristics that focused on fair and respectful treatment of the investigator by the IRB. Investigators wanted the opportunity to express disagreements with the IRB, and expressed dissatisfaction with their IRB if they perceived they were being treated disrespectfully. Reeser et al. (2008) used the IRB-RAT as a self-assessment tool for their institution; they found that an individual’s role in the institution’s research organization affected their perception of IRBs, and noted that research coordinators assigned lower scores to their IRB and perceived a lack of respect by the IRB.

In summary, the empirical studies evaluating IRB and REC performance differed in sample size, sampling characteristics, recruitment methods, data collection procedures, and analysis. The studies also evaluated performance in different ways. Nevertheless, the findings revealed two themes that appear to impact the evaluation of IRB and REC performance: IRB and REC protocol review processes and deliberations, and IRB and REC relationships with investigators. The studies provide a valuable opportunity for institutions to evaluate and improve their protocol review and deliberation processes, and strengthen relationships with investigators and others involved in conducting human subject research through respectful communication.

C. Conclusion

This paper examined key published advisory, regulatory, accreditation, and empirical literature focused on IRB performance. The need to evaluate the adequacy of IRB oversight of human subject research and to improve IRB oversight of human subject research is well supported in advisory, regulatory, accreditation, and empirical literature. Nevertheless, little
progress has been made to facilitate this evaluation since the 1997 OIG determination that IRBs have insufficient mechanisms to evaluate their effectiveness. Studies evaluating the adequacy and quality of IRB oversight of human subject protection remain limited. Further research exploring IRB quality measures is needed to identify an empirically based framework for IRB quality measures, including the perspectives of IRB members.
III. QUALITY MEASURES FOR INSTITUTIONAL REVIEW BOARDS:
WHAT IRB MEMBERS CONSIDER AND RECOMMEND

A. Introduction

Institutional review boards (IRBs) use ethical guidelines, federal regulations, and accreditation standards to oversee human subject research and play a critical role in human subject protection. Since the inception of IRBs in the 1970s, multiple advisory findings and regulatory reports have identified the need to evaluate IRB oversight of human subject protection. The need for IRB performance-focused reviews was first recognized in 1997 by the Department of Health and Human Services Offices of Inspector General. More recent recommendations to improve human subject protection and IRB oversight of research with human subjects were made by the existing Presidential Commission for the Study of Bioethical Issues (2011). Those recommendations included the development of a system to evaluate the effectiveness of programs and regulations responsible for human subject protection and the formation of empirically based methods to assess the protection of human subjects (Presidential Commission for the Study of Bioethical Issues, 2011). The 2011 Presidential Commission for the Study of Bioethical Issues recommendations provide evidence that little progress has been made to evaluate the adequacy and quality of IRB oversight of human subject protection. Accreditation literature has identified high-performing human subject protection practices at institutions with accredited programs but has not included empirical testing of these practices to evaluate the benefit for human subject protection (AAHRPP, 2011). Evaluation of the adequacy
and quality of IRB oversight of human subject research remains limited due to the lack of standard quality indicators and outcome measures for IRBs (DHHS, 2006).

To date, the majority of published studies exploring IRB performance have focused on operational and functional aspects of IRBs. These include studies exploring IRB membership (i.e., influence, roles and experience, characteristics and ethical attitudes, and level of participation in IRB meetings; Anderson, 2006; Campbell et al., 2003; Candelis et al., 2012; Lidz et al., 2012b; McNeil, Berglund, & Webster, 1994; Rothstein & Phuong, 2008; Sengupta & Lo, 2003). Whicher, Currie, and Taylor (2009) studied IRB members’ commitment to their role responsibilities, and Cook and Hoas (2011) examined how IRB members carry out their functions in overseeing human subject research. Studies have also examined variability in IRB protocol reviews for multi-site studies (McWilliams et al., 2003; Nowak, Bankert, & Nelson, 2006; Silverman, Hull, & Sugarman, 2010), IRB operational costs (Speckman et al., 2007; Sugarman et al., 2005; Wagner, Bhandari, Chadwick, & Nelson 2003; Wagner, Cruz, & Chadwick, 2004), IRB conflicts of interest (Wolf & Zandecki, 2007) and IRB policies related to safety reporting and subject compensation (Lieck, 2007; Paasche-Orlow & Brancati, 2005).

Efforts to evaluate components of IRB performance are evident in a growing number of studies published since 2006. Four studies evaluating IRB performance demonstrated the need to improve IRB protocol review processes and deliberations (Burris & Moss, 2006; Feldman & Rebholz, 2009; Wisner et al., 2011; Lidz et al., 2012b). Three other studies evaluating IRB performance identified the need to improve IRB communication with investigators (Keith-Spiegel et al., 2006; Reeser et al., 2008; Guillemin et al., 2012). Authors have made their evaluation tools available to the public in some cases. Tsan et al. explored the development of quality indicators for the Department of Veterans Affairs human subject protection programs and
later evaluated the effectiveness of those quality indicators (Tsan, Smith, & Baochong, 2010; Tsan, Nyugen, & Brooks, 2013). The authors published 16 outcome-focused quality indicators for the Department of Veterans Affairs human subject protection programs (Tsan et al., 2010). In early 2013, they reported on the use of those quality indicators to evaluate their 107 institutional human subject protection programs, and made a significant contribution to the empirical literature exploring outcomes of human subject protection programs (Tsan et al., 2013). Finally, Abbott and Grady’s (2011) systematic review of 43 studies evaluating IRBs identified the lack of any study that focused on the effect that IRB oversight had on human subjects, supporting a 2006 advisory recommendation made by the DHHS to consider the use of standard quality indicators and outcome measures to evaluate the effectiveness of IRB oversight of human subject protection.

Consideration of IRB quality measures from the perspective of IRB members has not been adequately explored. The purpose of this study was to explore IRB quality measures from the perspective of IRB members, and to examine member protocol review processes, protocol review quality, and role in human subject protection.

B. **Methods**

1. **Sample**

Purposeful sampling was used to recruit 10 IRB members from a large urban academic and research AAHRPP-accredited institution with approximately 80 IRB members serving on four IRBs that reviewed biomedical, social, and behavioral research protocols. Participating members presented diverse backgrounds in education, practice, service, and research; specialty areas included case management, community-based research, education, ethics, family therapy,
finance, health promotion, nursing, oncology, pharmacy, psychology, public health, and social services. Eight served as scientist members and had faculty appointments at their respective institutions; two non-scientist members represented the community and a vulnerable subject population. Nine served on a social-behavioral board, and the remaining member served on a biomedical board. Eight held doctorate degrees in ethics, nursing, pharmacy, psychology, public health, and social services, and one held a master’s degree in social sciences; the remaining member held a bachelor’s degree. Seven participating members were women. Members reported an estimated total of 78.5 years of IRB service, ranging from one year to 16 years. Six members had between seven and sixteen years of IRB services; the remaining four had five or fewer years of IRB service. The majority of IRB service years, 68.5 years, occurred at the participating institution; the remaining 10 years of outside IRB service for four members included board service in a community hospital, social service agency, and university.

2. Interview Guide

Interview guide questions were developed by the investigator based on a review of the literature (Appendix B). The questions were designed to facilitate discussion about improvement in the protocol review process and generate thoughts about IRB quality measures from the perspective of IRB members. Members were asked to describe the process, steps, and tools they used to complete protocol reviews, evaluate the quality of their reviews, and describe their role in human subject protection. They were also asked to share their thoughts about IRB quality measures and make recommendations. Open-ended questions were used to encourage an information-rich and insightful exploration (Patton, 2002) of the processes by which IRB members review protocols, and to illuminate what IRB members think about the need for IRB quality measures and what they consider as meaningful IRB quality measures.
3. **Data Collection Procedures**

After institutional review board approval for the study was obtained, a pilot interview was conducted in June of 2011 with an IRB member to obtain feedback on the organization and length of the interview guide; minor revisions were subsequently made to improve clarity. A recruitment statement was mailed electronically to IRB members of the participating institution in July of 2011 by the institution’s director of the human subject protection program; members interested in the study were invited to contact the investigator directly. Nine additional IRB members were enrolled between July and September of 2011. Telephone interviews were scheduled on a day and time convenient for members.

4. **Data Analysis**

Each member’s telephone interview was digitally recorded and transcribed. Field notes were written during each interview to record the investigator’s impressions of members’ responses to questions. The telephone interviews ranged from 32 to 61 minutes in duration and resulted in a total of 300 pages of interview transcripts. Identifiable information in the interview transcripts was removed. After interview transcripts were reviewed for content clarity, recordings were deleted from the digital recorder and desktop computer.

IRB members’ responses to interview questions were examined using thematic content analysis (Simons, Lathlean, & Squire, 2008). According to Simons et al. (2008), this form of inductive qualitative data analysis involves examining the content of data to identify data categories and expand the categories into themes. Two interview transcripts were selected to analyze the content of IRB member responses to questions and identify data categories. Three descriptive categories of data were identified, and included levels of protocol review and
protocol review processes, protocol review quality and subject protection, and recommendations for IRB quality measures. The categories were validated through a concurrent review by a committee member with expertise in qualitative research. Each transcribed interview was subsequently re-read and condensed into an interview summary reflecting the descriptive categories, resulting in 50 pages of interview summaries. Interview responses for each category were then grouped into category summaries to compare responses between members, identify themes in each category, and facilitate data analysis. Interview transcripts, interview summaries, and category summaries were cross-referenced during data analysis for clarification as needed.

C. Results

Three descriptive categories of qualitative data included levels of protocol review and protocol review processes, protocol review quality and subject protection, and recommendations for IRB quality measures. We look at each individually below.

1. Levels of Protocol Review and Protocol Review Processes

All 10 members participated in full board reviews of initial and continuing review applications, amendments, and prompt review reports. Nine of 10 completed expedited reviews of continuing review applications, amendments, responses to required modifications, and final reports. One member also reviewed exemption and expedited initial applications. Seven of eight scientist members functioned as primary and secondary reviewers for full board reviews; the remaining scientist member described a review system in which board members were expected to participate in all protocol reviews, with the chair designated as primary reviewer. One non-scientist member contributed as a secondary reviewer for research with vulnerable subjects; the community member contributed as a tertiary reviewer. Specialty areas of the social, behavioral,
and biomedical protocols were broad and included education, nursing, oncology, pharmacy, psychology, psychiatry, public health, and social services.

Members prioritized the consent process in their protocol reviews, including readability, clarity, and sensitivity of the consent language, and integrity and confidentiality in the consenting process. They looked for consistency in a protocol application to ensure that subject recruitment, participation, and compensation were similarly described in screening, recruitment, and consent materials. Scientist members examined the science and quality of the study to evaluate subject benefit. Members’ self-reported processes for completing protocol reviews are illustrated in Figure 1. Four scientist members described an inductive approach for their protocol reviews. They selected particular protocol components (most frequently, the consent form and research proposal) and reviewed these components first as a way to organize their review and examine the purpose of the study. These members then reviewed the protocol in its entirety, starting from the beginning. Two other scientist members described a deductive approach for their protocol reviews in which they reviewed the entire protocol from beginning to end to gain a general understanding of the study, and then focused on particular protocol components while reviewing the entire protocol in its entirety again. The remaining two scientist members described a closely matching three-step approach, including a conceptual step to understand the purpose of the study, a regulatory step to ensure the presence of all key elements, and a subject-focused step to examine the consent forms and evaluate subject protection and study integrity. One non-scientist member examined the research and its relationship to the community; the other used the Belmont principles to guide the member’s protocol reviews.
IRB SCIENTIST MEMBER PROCESSES FOR PROTOCOL REVIEWS

Inductive and Deductive Processes

Inductive Process  
N = 4

- Step 1: Select particular protocol components to review first (i.e., consent form and research proposal)
- Step 2: Use these components to organize review and examine study purpose.
- Step 3: Review the protocol in its entirety, from the beginning.

Deductive Process  
N = 2

- Step 1: Review the entire protocol for general understanding.
- Step 2: Focus on particular protocol components.
- Step 3: Reread the entire protocol with the particular components in mind.

Three-Part Process  
N = 2

- Conceptual
  - Understand study purpose
- Regulatory
  - Ensure presence of key required elements
- Subject-focused
  - Evaluate subject protection and study integrity

IRB NON-SCIENTIST MEMBER PROCESSES FOR PROTOCOL REVIEWS

N = 2

- Human Subjects
- Relationship to the community
- Belmont Principles

Figure 1. IRB Member Processes for Protocol Reviews.
Tools identified by members as facilitating their protocol reviews are summarized in Table I. The majority of members found the pre-reviews completed by IRB administrative staff helpful in facilitating protocol reviews. Scientist members believed the pre-review evaluated compliance with federal regulations and highlighted protocol issues needing a closer ethical review, like subject screening, recruitment, consent, and compensation. Scientist members also reported that IRB administrative staff’s communication with investigators facilitated members’ work, and acknowledged completing a protocol review more quickly when the protocol was well written and organized. One scientist member found an investigator-initiated cover letter to the IRB helpful in reviewing a protocol. Another scientist member found the regulatory compliance workbooks outlining elements of the Common Rule and developed by the human subject protection program’s quality improvement staff helpful in reviewing protocols. One non-scientist member found manuscripts or publications submitted by the investigator useful in understanding the investigator’s experience and purpose for the study; the other non-scientist member reviewed IRB meeting minutes completed by IRB administrative staff to recall earlier board discussions about a protocol.
### TABLE I
IRB MEMBER SELF-REPORTED TOOLS THAT FACILITATE PROTOCOL REVIEWS

<table>
<thead>
<tr>
<th>Tools</th>
<th>IRB Members</th>
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<tr>
<td>Pre-reviews completed by IRB administrative staff</td>
<td>Scientist and Non-scientist</td>
</tr>
<tr>
<td>IRB administrative staff communication with investigators</td>
<td>Scientist</td>
</tr>
<tr>
<td>Well written and organized protocol</td>
<td>Scientist</td>
</tr>
<tr>
<td>Investigator-initiated cover letter</td>
<td>Scientist</td>
</tr>
<tr>
<td>Regulatory compliance workbooks</td>
<td>Scientist</td>
</tr>
<tr>
<td>Investigator-submitted publications or manuscripts</td>
<td>Non-scientist</td>
</tr>
<tr>
<td>IRB meeting minutes</td>
<td>Non-scientist</td>
</tr>
</tbody>
</table>

Four scientist members described the regulatory compliance worksheets addressing mandatory elements of the *Common Rule* and required for each protocol review as helpful in outlining federal requirements for human subject protection, and acknowledged that the worksheets offered structure for their protocol reviews. Three of four scientist members who found the regulatory compliance worksheets useful had between 11 and 16 years of experiences. Three other scientist members described the worksheets as confusing and cumbersome, and believed the worksheets significantly hindered the review process. They believed revisions were needed to make the regulatory requirements clearer, and the worksheets more useful. Two of three scientist members who described the regulatory worksheet as confusing and cumbersome had five or fewer years of experience. The majority of members first typed or hand-wrote summary notes of their protocol reviews to facilitate full board discussions, and then completed the regulatory compliance worksheets; only one member relied entirely on the worksheet to organize protocol reviews. Finally, five of eight scientist members identified personal teaching and research responsibilities as a significant challenge to their IRB work. Their workload and time constraints limited the opportunity to directly communicate with investigators.
Consequently, scientist members found IRB administrative staff’s communication with investigators facilitative and supportive of their work.

2. **Protocol Review Quality and Subject Protection**

Members consistently described three key features of a quality protocol review: a thoughtful evaluation of subject protection, an ability to address compliance with federal research regulations, and an effective and meaningful oral presentation to the board. According to members, a quality protocol review required quality in content and delivery. One scientist member addressed all three features when describing a quality protocol review: “A quality review…I would say it’s thorough and addresses the major…regulatory issues… the reviewer provides an explanation of what study is about, and then summarizes specific issues related to the risk/benefit of study and consent process.” Another scientist member emphasized the oral presentation to the board: “The key element…in a quality review… is the presentation…can the member conceptually describe what is going on…so they’re not just telling me what’s missing but also what’s there? A quality review …critiques instead of narrating.” Still another scientist member emphasized written preparation for the oral presentation: “Written summary notes of a review contribute to a quality review because it requires more structure and detailed information.” The non-scientist members described a quality protocol review as “focusing on those parts of the application that relate to human subject protection, like compensation and safety… and subject recruitment and consent,” using subject protection to assess protocol review quality.

Members’ self-evaluation of protocol review quality did not consistently reflect their IRB service years. Four of ten members graded their protocol review quality with confidence at an A
or A-grade level; these members had between two and sixteen years of IRB service years. Of the remaining six members, three reported a grade level of B and B+, and thought the majority of their reviews were generally good in quality; these members had between one and eleven years of IRB service. Two members evaluated the quality of their protocol reviews as generally fair or mediocre, a C grade level; these members had between five and eleven years of IRB service. The remaining member with eleven years of IRB service acknowledged that the member’s protocol review quality varied, making it difficult to self-grade. This member reflected on the need to obtain feedback from investigators regarding the quality of protocol reviews completed by IRB members. Challenges to providing quality protocol reviews, summarized in Table II, included faculty teaching and research responsibilities, number of assigned protocol reviews, lack of time to complete written summaries of the reviews, and lack of clarity in research regulations, IRB application forms, and IRB review forms. Positive feedback from board members, as well as “social validation,” or comparison of one’s own full-board reviews to those of other members contributed to members’ estimation of their own protocol review quality.

### Table II
IRB Member Self-Reported Challenges in Protocol Review Completion

<table>
<thead>
<tr>
<th>Challenges</th>
<th>IRB Members</th>
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<tbody>
<tr>
<td>Faculty teaching responsibilities</td>
<td>Scientist</td>
</tr>
<tr>
<td>Faculty research responsibilities</td>
<td>Scientist</td>
</tr>
<tr>
<td>Number of assigned protocol reviews</td>
<td>Scientist</td>
</tr>
<tr>
<td>Lack of time to complete written summaries of the reviews</td>
<td>Scientist</td>
</tr>
<tr>
<td>Lack of clarity in research regulations</td>
<td>Scientist and Non-scientist</td>
</tr>
<tr>
<td>Lack of clarity in IRB application forms</td>
<td>Scientist and Non-scientist</td>
</tr>
<tr>
<td>Lack of clarity in IRB review forms</td>
<td>Scientist and Non-scientist</td>
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</table>
Members believed their primary responsibility was to ensure human subject protection, and seven of ten articulated a process by which they believed they protected human subjects. Four scientist members acknowledged a secondary role in human subject protection through their communication with and education of investigators. Another scientist member stressed the importance of open dialogue during IRB meetings to encourage communication and exchange between members. Still another scientist member acknowledged a secondary role in human subject protection by using a regulatory framework in reviewing protocols; a non-scientist member acknowledged a secondary role in human subject protection by using an ethical framework in reviewing protocols. Two remaining scientist members and one non-scientist member were unable to articulate a process by which they protected human subjects. One scientist member verbalized concern about the length and language in consent forms, and expressed doubts about whether or not the member was actually protecting human subjects,

I guess sometimes I don’t know that I’m doing that…I believe the consent forms are too long and too confusing. I don’t believe that the system is accomplishing it, and I’m part of the system…I think it’s everybody’s goal but…I’m not sure that the goal gets accomplished in part of because of all the rules and bureaucracy.

The majority of members believed they played a secondary role in protecting human subjects through their work with investigators, their regulatory and ethical framework, and open communication between members at IRB meetings.

3. **Recommendations for IRB Quality Measures**

Most members acknowledged not having previously used or considered IRB quality measures. However, the opportunity earlier in the interview to reflect on the process and quality
of protocol reviews and member role in human subject protection facilitated a thoughtful exploration of IRB quality measures. IRB members’ recommendations for IRB quality measures are summarized in Table III. One scientist member recommended, “…If you want to measure it, first make it more measurable.” This member recommended that the forms and processes by which an IRB protocol application are completed by investigators and reviewed by the IRB first be revised to improve clarity and streamline the application steps and review process, prior to measuring quality. Another scientist member believed that a great deal of information already exists for measuring quality of IRB work, and recommended aggregating existing data to examine the quality of worksheet completion by members, the quality of protocol review letters sent to investigators, as well as timely completion of protocol reviews by members and letters by IRB support staff.

The remaining members explored IRB quality measures at levels strikingly similar to the manner in which members had earlier described their role in human subject protection. One level or group of quality measures centered on human subjects; another group of quality measures centered on investigators; and the third group of quality measures centered on IRB members. Recommendations for IRB quality measures related to human subject protection included examining and improving the quality of the process and documentation of IRB review of subject complaints, injuries, and other unanticipated or adverse events related to the subject’s participation in the research. Another recommended quality measure related to human subject protection involved close monitoring of protocols for which human subject protection issues were identified. Recommendations for quality measures related to investigators focused on the importance of communication with investigators, including evaluating the usefulness of the protocol review letter for the investigator and the investigator’s response to the letter, and
evaluating the investigator’s general experience with the IRB and the degree to which the experience was informative, educational, and credible for the investigator. One scientist member acknowledged the concurrent importance of supporting the investigator’s role in protecting human subjects and subsequently improving the quality of the investigator’s research, “…Ultimately, that is what we are trying to do.” Another scientist member acknowledged that:

… we need to have a respectful, supportive relationship between the IRBs and investigators… you’d want … periodic feedback from investigators about how the IRB is communicating with them, whether the IRB … is treating them professionally, respectfully, and whether they think the IRB is keeping their focus on things that are in their purview in terms of human subjects … whether or not the IRB feedback is … helpful in building those protections into their work.
<table>
<thead>
<tr>
<th>Framework for Quality Measures</th>
<th>IRB Member Recommendations</th>
</tr>
</thead>
</table>
| Human subject protection-focused | Examine and improve the quality of the process and documentation of IRB review of subject complaints  
Examine and improve the quality of the process and documentation of IRB review of subject injuries  
Examine and improve the quality of the process and documentation of IRB review of other unanticipated or adverse events related to the subject’s participation  
Closely monitor protocols for which human subject protection issues were identified |
| Investigator-focused | Improve communication with investigators  
Evaluate usefulness of the protocol review letter for the investigator  
Evaluate investigator’s response to the protocol review letter  
Evaluate investigator’s general experience with the IRB and the degree to which the experience is informative, educational, and credible  
Support the investigator’s role in protecting human subjects and in improving the quality of the study |
| IRB member-focused | Develop a more systematic orientation for new members  
Promote mentoring opportunities for new members with senior members  
Provide peer evaluation and feedback between members  
Evaluate how board decisions are made  
Ensure that members remain competent with continuing education |
Recommendations for quality measures related to IRB members included developing more systematic orientation for new members, promoting mentoring opportunities for new members with senior members, members providing peer evaluation and feedback for each other, evaluating how board decisions are made as a board, and ensuring that members remain competent with continuing education.

D. **DISCUSSION**

To date, most research evaluating IRB performance has focused on improvements in IRB protocol review processes, deliberations, and communication with investigators. This study differed from other studies evaluating IRB performance because it explored IRB members’ descriptions of their protocol review processes prior to IRB deliberations, protocol review quality, role in human subject protection, and IRB quality measures. Member characteristics reflected variation in education; professional background and specialty expertise; and IRB role, experience, and length of service. This variation is important and encourages a wide perspective and view for exploring IRB quality measures.

Identification of differences in evaluative methods and steps used by members to review protocols is a unique finding of this study, and encourages innovative changes in IRB protocol review processes and deliberations and improvement of IRB member orientation and workload. The findings also illustrate that members identified different tools as facilitating their protocol reviews. Incorporation of those tools into new IRB member orientation, as well as the development of other tools to facilitate protocol reviews, would support quality improvement efforts for human subject protection programs.
Both scientific and nonscientific members articulated ethical principles during the interviews while describing their protocol review processes, suggesting that they used an ethical framework to review IRB protocols. They reported focusing on subject screening, selection, recruitment, and compensation. Scientific members reported examining the science and quality of a protocol to evaluate the risks and benefits for subjects. Taylor (2007) recommended the development of measures to evaluate whether IRB protocol reviews include an ethical evaluation of proposed research. Objective measures of IRB ethical considerations would increase IRB credibility with investigators and provide institutions an opportunity to enhance their IRB protocol review processes and deliberations. The measures would also address recommendations made by Cook and Hoas (2011) to provide objective data on how IRBs protect the rights and welfare of human subjects.

Consistent with findings from Lidz et al. (2012a) and Cook and Hoas (2011) regarding IRB committee focus on consent forms and processes, members reported prioritizing the consent form and processes when completing protocol reviews. The focus on consent forms and processes may reflect the study institution’s awareness of long-standing deficiencies related to informed consent previously identified in OHRP publications and the subsequent need to outline this Common Rule element clearly in protocol review forms. Also consistent with findings from Cook and Hoas (2011), the majority of members reported reviewing the research proposal to clarify elements of the investigator’s research plan. These findings have implications for new investigator training regarding the need for clearly written research protocols and informed consent forms and procedures to facilitate IRB review, deliberations, and approval of protocol applications.
Important to note was the scientific members’ attention to regulatory requirements even while they articulated ethical principles when describing their protocol review processes. Scientific members stressed the importance of addressing regulatory requirements when responding to interview questions about protocol review processes and quality. Almost one-half of scientific members described the regulatory compliance worksheets outlining elements of the *Common Rule* and mandatory for completing protocol reviews as helpful in outlining federal requirements for human subject protection; one scientific member described the quality improvement regulatory compliance workbook as useful. When exploring their protocol review processes, scientific members described a regulatory step in their review “to ensure the presence of all key elements.” Additionally, scientific members identified the ability to address compliance with federal research regulations as an important feature of a quality protocol review. These findings suggest that scientific members addressed mandatory elements of the *Common Rule* during their protocol reviews and deliberations, and differ from the Lidz et al. (2012a) findings.

The need to write summary notes of protocol reviews to supplement completion of mandatory worksheets by the majority of scientific members suggests that their evaluative processes for reviewing protocols differ from the structure and organization of the worksheets. It also suggests the need for alternative ways to document IRB ethical considerations when evaluating proposed research. A number of scientific members expressed concern at the lack of clarity in the worksheets. The need to write supplemental summary notes as well as the lack of clarity in the worksheets reflect the need to improve regulatory worksheets to increase clarity and lessen the burden and workload for IRB members.
Study findings regarding IRB members’ commitment to their role were consistent with those of Cook and Hoas (2011) and Whicher et al. (2009). Members verbalized a commitment to their IRB work, and described their IRB work as a rewarding and positive experience. Members with a longer history of IRB service described completing protocol reviews more efficiently when they were familiar with the protocol and earlier deliberations about the protocol. Similar to findings by Feldman and Rebholz (2009), members identified a need for more continuing education on research ethics and compliance. The majority of scientific and nonscientific members described the opportunity to learn from other members as important; they also expressed the belief that their deliberations were productive.

Perhaps the most significant and unique contribution of this study is the thoughtful exploration of IRB quality measures from the perspective of IRB members. Members described quality measures that focused on enhancement of human subject protection; these included the evaluation and improvement in the processes and documentation of IRB review of subject complaints, injuries, and unanticipated or adverse events, as well as close monitoring of protocols for which human subject protection issues were identified. Members also identified investigator-focused quality measures, including the evaluation of investigator satisfaction with IRB communication and usefulness of protocol review letters. The third group of IRB quality measures focused on IRB member education, mentoring, and peer review.

Several study limitations require consideration. Although members reflected a diverse background, the results may not reflect the experiences of IRB members at the study institution who did not participate in the study, or IRB members at other institutions. Additionally, the findings do not reflect data saturation due to the limited number of interviews conducted to
ensure an information-rich and insightful exploration of IRB member protocol review processes and IRB quality measures (Patton, 2002).

In summary, future improvements of IRB oversight of human subject research need to consider the use of standard IRB quality measures to evaluate the adequacy of this oversight. This study offers a beginning framework for the development of these measures. Opportunities for future exploration of IRB quality measures include the use of a larger sample size of IRB members, participation of multiple institutions, and use of focus groups with IRB members as a basis for developing a quantitative survey.


Retrieved from http://iom.edu/Reports/Preserving-Public-Accreditation-and-Human-Participant-Protection-Programs


Appendices
Appendix A

IRB PERFORMANCE: ADVISORY AND REGULATORY REPORTS (1979-2011)

<table>
<thead>
<tr>
<th>Advisory/Regulatory Report</th>
<th>Advisory/Regulatory Body</th>
<th>Year of Report</th>
</tr>
</thead>
<tbody>
<tr>
<td>Institutional Review Boards: Their Role in Reviewing Approved Research</td>
<td>Department of Health and Human Services, Office of the Inspector General, Office of Evaluation and Inspections</td>
<td>1998c</td>
</tr>
<tr>
<td>Ethical and policy issues in international research: Clinical trials in developing countries</td>
<td>National Bioethics Advisory Commission (1996-2001)</td>
<td>2001a</td>
</tr>
<tr>
<td>Ethical and policy issues in research involving human participants</td>
<td>National Bioethics Advisory Commission (1996-2001)</td>
<td>2001b</td>
</tr>
<tr>
<td>PCBE Transcripts: Session 2: Regulation 6: Institutional Review Boards (IRBs);</td>
<td>E. J. Emanuel, MD, PhD (September 12, 2002); President’s Council on Bioethics (2001-2009)</td>
<td>2002</td>
</tr>
<tr>
<td>OHRP compliance oversight activities: significant findings and concerns of noncompliance.</td>
<td>Department of Health and Human Services, Office for Human Research Protections, division of Compliance Oversight</td>
<td>2005</td>
</tr>
<tr>
<td>Recent compliance oversight determinations.</td>
<td>Department of Health and Human Services, Office for Human Research Protections, Division of Compliance Oversight</td>
<td>2009</td>
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</table>
## Appendix B

### IRB MEMBER INTERVIEW GUIDE

| Background questions                      | What is your professional background? |
|                                         | What type of IRB do you serve?        |
|                                         | How long have you been on this IRB?  |
|                                         | What role/position do you have in this IRB (community member, scientist member, and so forth)? |
|                                         | Have you served on other IRBs? What kind? In what role/position? |
|                                         | What kind of protocol reviews do you complete? |
|                                         | What kind of review system does your institution use? E.g. Primary /secondary |

| Process for and quality of protocol reviews/role in human subject protection | How do you go about reviewing a protocol? What process do you use? Please explain. |
|                                                                           | What influences your review of a protocol? Please explain. |
|                                                                           | When you review a protocol, where do you place your emphasis? Please explain. |
|                                                                           | What things help you in your review of a protocol? Please explain. |
|                                                                           | What tools or practices do you use to complete your reviews? Can you give me an example of what you mean? Please explain. |
|                                                                           | How does this tool/practice help improve the quality of your reviews? How so? |
|                                                                           | What makes a protocol review a quality protocol review? Can you give me an example of what you mean? What factors do you believe contribute to a quality review? Please explain. |
|                                                                           | For the protocols you review, how would you evaluate the quality of those reviews? Please explain. |
|                                                                           | What letter grade would you give yourself for your protocol reviews? Why? |
|                                                                           | What challenges make it difficult to make your reviews the quality that you would like? Please explain. |
|                                                                           | How do you know you’re doing a good job as an IRB member? Can you give me an example? |
|                                                                           | How do you know you’re protecting human subjects? Can you give me an example? |

| Standard quality measures for IRBs | What do you think about the development of standard quality measures for institutional review boards? Can you elaborate? If not, why not? |
|                                   | What would you recommend these measures include? Can you give me some examples of measures that you recommend? |
|                                   | How would these measures help you improve the quality of your protocol reviews? |

| Conclusion                        | Is there anything else you would like to share before we complete our phone interview? |
|                                   | Do you have any questions for me? |
|                                   | Is it alright to contact you if I have any follow-up questions or need for clarification? |
|                                   | Would you like a typed copy of your transcript or any final report or publication that results from my interviews? |
Exemption Granted

March 15, 2010

Ursula M. Brozek, MS, RN
Health Systems Science
Advancement and Comm. Relations
845 S Damen, M/C 802
Chicago, IL 60612
Phone: (312) 996-8883 / Fax: (312) 996-3512

RE: Research Protocol # 2010-0206
“Performance Measures for Institutional Review Boards”

Dear Ms. Brozek:

Your Claim of Exemption was reviewed on March 12, 2010 and it was determined that your research protocol meets the criteria for exemption as defined in the U. S. Department of Health and Human Services Regulations for the Protection of Human Subjects [(45 CFR 46.101(b)]. You may now begin your research.

Exemption Period: March 12, 2010 – March 11, 2013

Your research may be conducted at UIC and with adult subjects only.

The specific exemption category under 45 CFR 46.101(b) is:
(2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

You are reminded that investigators whose research involving human subjects is determined to be exempt from the federal regulations for the protection of human subjects still have responsibilities for the ethical conduct of the research under state law and UIC policy. Please be aware of the following UIC policies and responsibilities for investigators:
1. **Amendments** You are responsible for reporting any amendments to your research protocol that may affect the determination of the exemption and may result in your research no longer being eligible for the exemption that has been granted.

2. **Record Keeping** You are responsible for maintaining a copy all research related records in a secure location in the event future verification is necessary, at a minimum these documents include: the research protocol, the claim of exemption application, all questionnaires, survey instruments, interview questions and/or data collection instruments associated with this research protocol, recruiting or advertising materials, any consent forms or information sheets given to subjects, or any other pertinent documents.

3. **Final Report** When you have completed work on your research protocol, you should submit a final report to the Office for Protection of Research Subjects (OPRS).

4. **Information for Human Subjects** UIC Policy requires investigators to provide information about the research protocol to subjects and to obtain their permission prior to their participating in the research. The information about the research protocol should be presented to subjects in writing or orally from a written script. *When appropriate,* the following information must be provided to all research subjects participating in exempt studies:
   a. The researchers affiliation; UIC, JBVMAC or other institutions,
   b. The purpose of the research,
   c. The extent of the subject’s involvement and an explanation of the procedures to be followed,
   d. Whether the information being collected will be used for any purposes other than the proposed research,
   e. A description of the procedures to protect the privacy of subjects and the confidentiality of the research information and data,
   f. Description of any reasonable foreseeable risks,
   g. Description of anticipated benefit,
   h. A statement that participation is voluntary and subjects can refuse to participate or can stop at any time,
   i. A statement that the researcher is available to answer any questions that the subject may have and which includes the name and phone number of the investigator(s).
   j. A statement that the UIC IRB/OPRS or JBVMAC Patient Advocate Office is available if there are questions about subject’s rights, which includes the appropriate phone numbers.

Please be sure to:

→ Use your research protocol number (listed above) on any documents or correspondence with the IRB concerning your research protocol.

We wish you the best as you conduct your research. If you have any questions or need further help, please contact me at (312) 355-2908 or the OPRS office at (312) 996-1711. Please send any correspondence about this protocol to OPRS at 203 AOB, M/C 672.

Sincerely,
Charles W. Hoehne, CIP
Assistant Director, IRB # 2
Office for the Protection of Research Subjects

Enclosure(s): None

cc: Arlene Miller, Health Systems Science, M/C 802
    Beverly J. McElmurry, Health Systems Science, M/C 802
Appendix D

Exemption Determination
Amendment to Research Protocol – Exempt Review
UIC Amendment # 1

April 11, 2011

Ursula M. Brozek, MS, RN
Health Systems Science
845 S Damen, M/C 802
Chicago, IL 60612
Phone: (312) 996-8883 / Fax: (312) 996-3512

RE: Protocol # 2010-0206
“Performance Measures for Institutional Review Boards”

Dear Dr. Brozek:

The OPRS staff/members of Institutional Review Board (IRB) #2 have reviewed this amendment to your research, and have determined that your research protocol continues to meet the criteria for exemption as defined in the U. S. Department of Health and Human Services Regulations for the Protection of Human Subjects [(45 CFR 46.101(b)].

The specific exemption category under 45 CFR 46.101(b) continues to be:

1) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

You may now implement the amendment in your research.

Please note the following information about your approved amendment:

Amendment Approval Date: April 11, 2011
Amendment:
Summary: UIC Amendment #1 dated March 23, 2011 and submitted to OPRS on March 29, 2011 is an investigator-initiated amendment:
1) Change in Faculty Sponsor from Beverly J. McElmurry to Eileen Collins
2) Submission of the “E-Mail Message to IRB Chairs/Directors” (Version #1, dated March 23, 2011)
3) Revised Recruitment Statement (Version #2, dated March 23, 2011)
6) Addition of Naimah Malik as a transcriptionist

You are reminded that investigators whose research involving human subjects is determined to be exempt from the federal regulations for the protection of human subjects still have responsibilities for the ethical conduct of the research under state law and UIC policy. Please be aware of the following UIC policies and responsibilities for investigators:

5. **Amendments** You are responsible for reporting any amendments to your research protocol that may affect the determination of the exemption and may result in your research no longer being eligible for the exemption that has been granted.

6. **Record Keeping** You are responsible for maintaining a copy all research related records in a secure location in the event future verification is necessary, at a minimum these documents include: the research protocol, the claim of exemption application, all questionnaires, survey instruments, interview questions and/or data collection instruments associated with this research protocol, recruiting or advertising materials, any consent forms or information sheets given to subjects, or any other pertinent documents.

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8. **Information for Human Subjects** UIC Policy requires investigators to provide information about the research protocol to subjects and to obtain their permission prior to their participating in the research. The information about the research protocol should be presented to subjects in writing or orally from a written script. **When appropriate**, the following information must be provided to all research subjects participating in exempt studies:
   f. The researchers affiliation; UIC, JB VAMC or other institutions,
   g. The purpose of the research,
   h. The extent of the subject’s involvement and an explanation of the procedures to be followed,
   i. Whether the information being collected will be used for any purposes other than the proposed research,
   j. A description of the procedures to protect the privacy of subjects and the confidentiality of the research information and data,
   f. Description of any reasonable foreseeable risks,
   k. Description of anticipated benefit,
   l. A statement that participation is voluntary and subjects can refuse to participate or can stop at any time,
   m. A statement that the researcher is available to answer any questions that the subject may have and which includes the name and phone number of the investigator(s).
n. A statement that the UIC IRB/OPRS or JB VAMC Patient Advocate Office is available if there are questions about subject’s rights, which includes the appropriate phone numbers.

Please be sure to:

➔ Use your research protocol number (2010-0206) on any documents or correspondence with the IRB concerning your research protocol.

We wish you the best as you conduct your research. If you have any questions or need further help, please contact me at (312) 355-2908 or the OPRS office at (312) 996-1711. Please send any correspondence about this protocol to OPRS at 203 AOB, M/C 672.

Sincerely,

Charles W. Hoehne, B.S., C.I.P.
Assistant Director, IRB # 2
Office for the Protection of Research Subjects

cc: Arlene Miller, Health Systems Science, M/C 802
    Eileen Collins, Health Systems Science, M/C 802
VITA
Ursula Brozek, MS, RN

EDUCATION

<table>
<thead>
<tr>
<th>Degree</th>
<th>Dates</th>
<th>Major</th>
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<tbody>
<tr>
<td>University of Illinois at Chicago</td>
<td>1978-1981</td>
<td>Nursing</td>
</tr>
<tr>
<td>Chicago, Illinois</td>
<td></td>
<td>MS</td>
</tr>
<tr>
<td>Saint Xavier University</td>
<td>1973-1977</td>
<td>Nursing</td>
</tr>
<tr>
<td>Chicago, Illinois</td>
<td></td>
<td>BS</td>
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LICENSURE
State of Illinois: Registered Nurse (Active)

PROFESSIONAL EXPERIENCE

<table>
<thead>
<tr>
<th>Date</th>
<th>Position</th>
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<tbody>
<tr>
<td>2008-Present</td>
<td>Compliance and Quality Specialist, Nursing Practice, University of Illinois Hospital, Chicago, IL</td>
</tr>
<tr>
<td>2000-Present</td>
<td>Compliance and Privacy Officer, College of Nursing, University of Illinois at Chicago, Chicago, IL</td>
</tr>
<tr>
<td>1999-2000</td>
<td>Visiting Clinical Instructor, Saint Xavier University, Chicago, IL Health Care Consultant, Riveredge Psychiatric Hospital, Forest Park, IL</td>
</tr>
<tr>
<td>1997-1999</td>
<td>Chief Nursing Officer, Woodland Behavioral Health Hospital, Schaumburg, IL</td>
</tr>
<tr>
<td>1992-1997</td>
<td>Regional Director, Clinical Support Services, Horizon Health Corporation, Denton, TX</td>
</tr>
<tr>
<td>1988-1992</td>
<td>Nurse Manager, Mental Health Services, University of Chicago Hospitals, Chicago, IL</td>
</tr>
<tr>
<td>1987-1988</td>
<td>Nurse Manager, Mental Health Services, Michael Reese Hospital, Chicago, IL</td>
</tr>
<tr>
<td>1981-1987</td>
<td>Nurse Therapist, Lake County Health Department, Lake County, IL</td>
</tr>
<tr>
<td>1977-1981</td>
<td>Staff Nurse/Supervisor, Michael Reese Hospital, Chicago, IL</td>
</tr>
</tbody>
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REGULATORY COMPLIANCE EXPERTISE

- Oversee credentialing and privileging activities for all advanced practice nurses for academic faculty practice and medical center; established credentialing and privileging processes and systems for advanced practice nurses for academic faculty practice and hospital-based practice; developed and educated advanced practice nurses regarding specialty-based competencies for privileges.
- Provide oversight of regulatory compliance and risk management components for academic faculty practice.
- Develop resource materials and provide faculty education in areas of contract management, risk management, FERPA, PIPA, HIPAA privacy and security compliance, and management of high risk data.
- Participate as faculty member of University-based Institutional Review Board reviews of biomedical, social and behavioral research protocols; participated in University-based preparation for research accreditation by the Association for the Accreditation of Human Research Protection Programs.
- Participate as member of University-wide compliance governance committee addressing clinical and billing practices for academic faculty practice.
- Facilitated preparation for, and participated in multiple Joint Commission surveys for hospital-based behavioral health programs, including inpatient, outpatient and home health components. Activities included policy/procedure development, staff development, and mock surveys.
- Successfully obtained Medicare exemption, state licensure, state certification, and fiscal intermediary approval for multiple hospital-based behavioral health programs in numerous states, including Illinois, Ohio, Wisconsin, Michigan, Kentucky, and Tennessee. Extensive familiarity and expertise in operationalizing and implementing Medicare, state licensure, state certification, fiscal intermediary and professional practice regulations for hospital clients.
- Completed clinical and operational risk management audits of multiple hospital-based behavioral health programs in numerous states to evaluate compliance with Medicare, state, fiscal intermediary and professional practice regulatory requirements following initial exemptions, licensure and certification.

RISK MANAGEMENT EXPERTISE

- Directed data collection, analysis, reports and corrective action for occurrence report activity, probable claim report activity, and patient advocate services.
- Worked with law firms to obtain legal consultation related to policy development, interpretation of state laws, and responses to complaints.
- Reviewed and completed revisions in bylaws and rules and regulations for hospital-based nursing and medical staff.
- Reviewed and completed revisions in bylaws for academic nursing faculty practice.

PROFESSIONAL MEMBERSHIPS
Sigma Theta Tau International Honor Society of Nursing, 1977-Present

PRESENTATIONS


Brozek, U. (2000). Roles and Responsibilities of a Compliance Officer, and, Hospital Survey Requirements; Presentation made for Zen Sha Ren nurse administrators from Japan on behalf of Global Health Leadership, College of Nursing, Chicago, IL.

Brozek, U. (2002). Managing Contracts for Research Studies; Presentation made for nursing faculty on behalf of Center for Research Facilitation, College of Nursing, Chicago, IL.

Brozek, U. (2002). Advanced Nursing Practice; Presentation made for Zen Sha Ren Nurse Administrators from Japan on behalf of Global Health Leadership, College of Nursing, Chicago, IL.

Brozek, U. (2003). HIPAA: Implications for Nursing Research; Presentation made for nursing faculty on behalf of Center for Research Facilitation, College of Nursing, Chicago, IL.


Brozek, U. (2003). JCAHO Standards for Nursing Practice and Education of Nurses; Contributor to workshop for nurse administrators from Yatsushiro General Hospital, Japan on behalf of Global Health Leadership, College of Nursing, Chicago, IL.


Brozek, U. (2004). Integrating Primary Health Care in a Psychiatric Rehabilitation Program; Contributor to presentation made for the International Association of Psychosocial Rehabilitation Services, San Diego, CA.

Brozek, U. (2006). *JCAHO Hospital Accreditation Standards and Applicability to Curriculum Development for Trauma/Critical Care Education*: Contributor to workshop for nurse faculty from The Thai Red Cross College of Nursing on behalf of Global Health Leadership, College of Nursing, Chicago, IL.


**PUBLICATIONS**


**CONSULTATION ENGAGEMENTS AND SERVICES FOR THE UIC COLLEGE OF NURSING, NURSING SERVICE PLAN, 2000-2005**

*Cascade Psychiatric Services:* provided regulatory expertise via a subcontract with hospital in Seattle, WA to re-open gero-psychiatric unit and prepare it for Medicare exemption, Washington Departments of Health and Mental Health licensure and certification surveys, JCAHO survey, educate nursing staff on patient safety, rights and confidentiality, review policies and procedures and make recommendations for revisions, and mentor unit nursing leadership (October 2004 through March 2005).

*Illinois Department of Finance and Professional Regulations:* provided expert witness work for IDFPR (September 2003 through June 2004).

*Managed Care Partners, Inc:* provided regulatory expertise via a subcontract with hospital in Michigan to re-open gero-psychiatric unit and prepare it for Medicare exemption, Michigan Departments of Health and Mental Health licensure and certification surveys, JCAHO survey, educate nursing staff on patient safety, rights and confidentiality, write policies and procedures and mentor unit nursing leadership (August 2000 through August 2001).

*Medical College of Georgia School of Nursing:* provided faculty practice expertise to evaluate status of faculty practice plan implementation and make recommendations to operationalize the School’s faculty practice plan (October 2004 through June 2005).

*Medical Outsourcing Services:* provided HIPAA privacy regulatory expertise for medical diagnostic imaging company to develop policies and procedures and staff education to ensure compliance with HIPAA privacy regulations (March 2004 through September 2004).

*Wolcott, Wood and Taylor, Inc,:* provided HIPAA privacy regulatory expertise for UIC COM MSP physician billing company to ensure compliance with HIPAA privacy regulations (March 2001 through June 2003).