

Protecting the Teaching and Learning Environment: A Hybrid Model for Human Subject Research Public Policy Implementation

Kristi N. Hottenstein, Ph.D.
University of Michigan-Flint

Abstract: *Regulations for research involving human subjects have long been a critical issue in higher education. Federal public policy for research involving human subjects impacts institutions of higher education by requiring all federally funded research to be passed by an Institutional Review Board (IRB). Undergraduate research is no exception. Given the literature on the benefits of undergraduate research to students, faculty, and institutions, how human subject research public policy is being implemented at the undergraduate level was a significant gap in the literature because how these public policies are implemented impacts undergraduate research. This qualitative, single-case study examined the human subject research policies and practices of a selective, Mid-western, Council on Undergraduate Research institution. The purpose of the study was to determine how this institution implemented human subject research public policy to benefit its students. This institution used a hybrid approach of public policy implementation that met federal requirements while capitalizing on the role local actors can play in the implementation process. This model resulted in a student-friendly implementation emphasizing various learning outcomes and student mentoring. Although there is considerable research and public discussion on the negative aspects of IRBs, if approached in a manner that embraces student learning, the IRB experience can be an extremely beneficial aspect of the institution's learning environment.*

Keywords: *Undergraduate research, institutional review board, public policy, human subject research*

Introduction

Concern over the impact federal regulations have on the internal affairs of higher education institutions remains a critical issue in higher education (Dash, 2007; Feeley, 2007; Hemmings, 2006; Jaschik, 2008; Stark, 2012; White, 2007). Protection of human subjects is one area that the Federal government has promulgated policy through its agencies to influence higher education policy and action at the institutional level. Federal public policy for research involving human subjects, better known as the Common Rule, impacts higher education institutions by requiring all federally funded research to be passed by an institutional review board. The influences of this federal policy determine institutional and faculty ability to gain access to federal research funds (U.S. Department of Health and Human Services, 1999). In light of the value of undergraduate research to colleges and universities, one would have expected to find studies that examined the relationship between the institutional review board and undergraduate research. Unfortunately, these types of studies do not exist.

Undergraduate Research

Undergraduate research benefits students, faculty, and institutions. Student benefits include: increases in retention, intellectual gains, skill attainment, graduate school placement and career preparation (Crowe & Brakke, 2008; Hathaway, Nagda, & Gregerman, 2002; Ishiyama, 2002). Faculty benefits include: increased lab assistance, ongoing research opportunities, and assistance with tenure and promotion (Corley, 2013; Nagda, Gregerman, Jonides, von Hippel, & Lerner, 1998). Institutional benefits include: increased admissions selectivity, increased institutional funding, and lower attrition rates (Kierniesky, 2005; Nagda, et al., 1998). In 1998, *Reinventing Undergraduate Education: A Blueprint for America's Research Universities* was published by the Boyer Commission on Educating Undergraduates in the Research University. The report called for increased involvement of undergraduates in faculty-mentored research experiences. This led to increased funding through the National Science Foundation, the National Institutes of Health, and the Howard Hughes Medical Institute to support American colleges and universities in creating opportunities for authentic research experiences for undergraduate students across multiple disciplines (Adedokun, Carleton Parker, Bessenbacher, Childress, & Daniels Burgess, 2012; Hunter, Laursen, & Seymour, 2006).

In 2002, The Association of American Colleges and Universities advocated for additional attention on undergraduate research calling it a key means to engage students, and in its 2007 *College Learning for the New Global Century* report, it recommended undergraduate research as a key focus area. In 2005, National Survey of Student Engagement included undergraduate research as an indicator for effective teaching (Corley, 2013). Kuh (2008) listed undergraduate research as one of ten high-impact educational practices beneficial to students and Lopatto (2006) discussed how undergraduate research engages students in active learning, provides academic challenge, and creates student-faculty interaction in ways that meet student engagement benchmarks reflected in the National Survey on Student Engagement (NSSE). The literature reflects a multitude of well-researched benefits of undergraduate research as well as a call for institutions to increased involvement in undergraduate research. Given this, it is important to understand the policies that regulate undergraduate research. Most notably, undergraduate research, as with all human subjects research conducted on the campuses of American colleges and universities, requires institutional review board approval and monitoring.

Institutional Review Boards

In 2008, there were more than 5,500 IRBs nationwide providing oversight to any federally funded project, and a large amount of unfunded research (Sanders & Ballengee-Morris, 2008). In a published report titled *Research on Human Subjects: Academic Freedom and the Institutional Review Board*, the American Association of University Professors (2006) spoke out strongly against IRB policies and practices stating, "there could hardly be a more obvious potential threat to academic freedom" (p. 1). Stark (2007) argued that the regulations aimed to protect the rights of human subjects actually violated the rights of researchers. Furthermore, some research indicated a handful of isolated, unethical practices may have created a spiral of knee-jerk reactions resulting in a loss of academic freedom, and a laundry list of other problems for researchers

(White, 2007). The Office of Human Research Protection database now contains over 10,500 records of registered IRBs (U.S. Department of Health and Human Services, 2016).

The basic provisions of the FCR Title 45 Part 46, better known as the Common Rule, were written in such a way that allowed for institutional interpretation and discretion. Institutional discretion impacts how the regulations are actually implemented at the institution. The literature reviewed reflected a variety of different interpretations of this Federal policy, as well as a variety of different implementation models being used to carry out federal human subject research public policy at the institutional level.

It appears institutional review boards are a permanent part of higher education. If undergraduate research truly is the pedagogy of the 21st century, more disciplines, departments, and researchers will find their research going before IRBs. Understanding how IRBs are implementing human subject research public policy is beneficial to researchers, institutions, and IRBs. First, it assists other institutions in examining their IRB implementation strategies and practices and can help them implement best practices. Understanding how a Council on Undergraduate Research institution is implementing human subject research public policy for undergraduate research may help to shape future policy on the issue. Research on the IRB role and function as it pertains to the implementation of Federal regulations clarifies IRB scope of practice, and a clearly defined scope of practice can help to inform researchers on ethical practices. Lastly, providing stakeholders (faculty, staff, and students) with a clearer understanding of how IRBs are implementing human subject research public policy can aid in alleviating some of the contention that is so prevalent in the literature.

Policy Implementation Theory

I approached this research through a public policy implementation theory lens. Public policy implementation was one of the earliest topics addressed by policy analysts. The implementation of policy is not a uniform process. Implementation varies by policy type, each type possessing a different degree of implementation difficulty. Although regulatory policies such as the Common Rule may seek harmony, an entity, in this case higher education, affected by the policy can be contentious (deLeon & deLeon, 2002). This contention was evident throughout the literature reviewed.

Policy implementation theories can be broadly categorized into three groups: top-down theories, bottom-up theories, and hybrid theories. Top-down approaches are based on the premise that implementation of policy begins with a decision made by government. Top-down theories disregard the impact of implementers (Pulzl & Trieb, 2007). Bottom-up approaches take a counter approach to policy implementation, emphasizing the role of local actors in the policy implementation process, noting the importance of those actually involved with delivering the policy. As researchers developed and analyzed the pros and cons of top-down and bottom-up approaches, hybrid theories of implementation emerged. Top-down and bottom-up scholars

agreed policy implementation is “a continuum located between central guidance and local autonomy” (Pulzl & Trieb, 2007, p. 100). Hybrid models mold the relevant aspects of both approaches into a middle ground. Hybrid models understand the importance of top-down aspects such as centrally defined policy decision, but also appreciate and value the need to involve lower-level actors.

Ripley’s Model of the Policy Process

Randall Ripley is a public policy theorist known for his hybrid approach to the public policy process. Ripley’s approach highlights the connections between the environment, governmental policy activity, social policy activity, and the political actors’ perceptions of the environment. Using Ripley’s (2010) conceptual model, I identified the environment as the institution, the policy actors as the IRB chair, IRB members, and undergraduate research advisors/mentors, the governmental policy activity as the federal policy to protect human subjects, and the social policy activity as undergraduate research. Figure 1 below illustrates how Ripley’s model can be adapted to inform the implementation of human subject research public policy implementation at the institutional level.

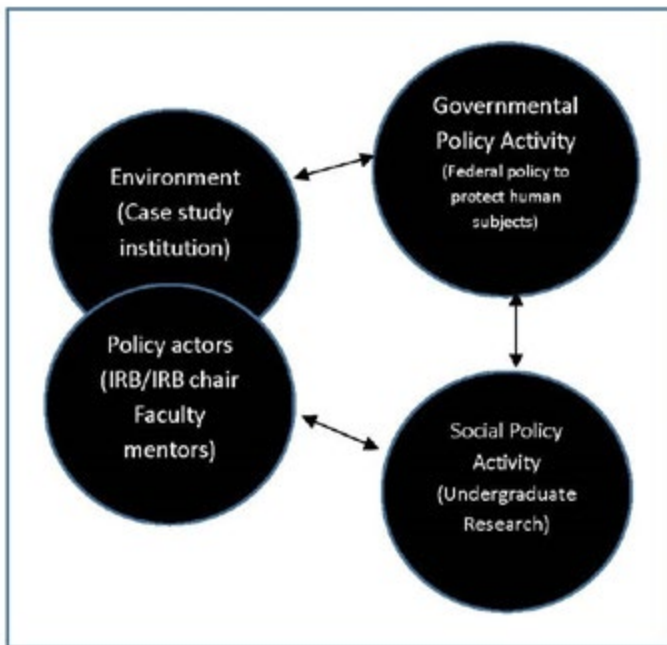


Figure 1. Illustration of how Ripley’s model was applied to analyze human subject research public policy implementation at the institutional (Adapted from Ripley’s General Model, 2010).

Theme-Centered versus Project-Centered

This study examined the implementation of a Federal protective, regulatory policy at the institutional level, specifically, federal human subject research public policy as defined in the Code of Federal Regulations, Title 45, Part 46. Purposeful sampling was used by the researcher to select the case study institution. Some scripts have been modified in an attempt to provide anonymity to the institution. For the purposes of anonymity, the selected institution will be referred to throughout the remainder of this document by the pseudonym, MRC. MRC is a selective, Midwestern, Council on Undergraduate Research affiliated institution, intensely focused on undergraduate research.

The methodology was a qualitative, single-case study. Semi-structured interviews and methodological triangulation were used to gather data which was then analyzed using NVivo 11 qualitative software. While the literature review covered undergraduate research and IRBs respectively, a significant gap in the literature existed as to how federal human subject research regulations were being implemented at the undergraduate level. Taking an in-depth look at how these regulations are implemented by an IRB at a CUR institution where undergraduate research is a significant portion of the undergraduate experience has helped us to better understand this connection.

Findings

The literature reviewed for this case study presented arguments for the value of a quality undergraduate research program. From high impact best practices, to the pedagogy of the 21st century, to increased job and graduate school placement rates, the arguments for a quality undergraduate research program were abundant. The purpose of this study was to determine how one institution has implemented human subject research public policy to benefit its students.

Four main themes, some with subsequent subthemes, emerged from the data. Figure 2 below illustrates the themes and subthemes found.

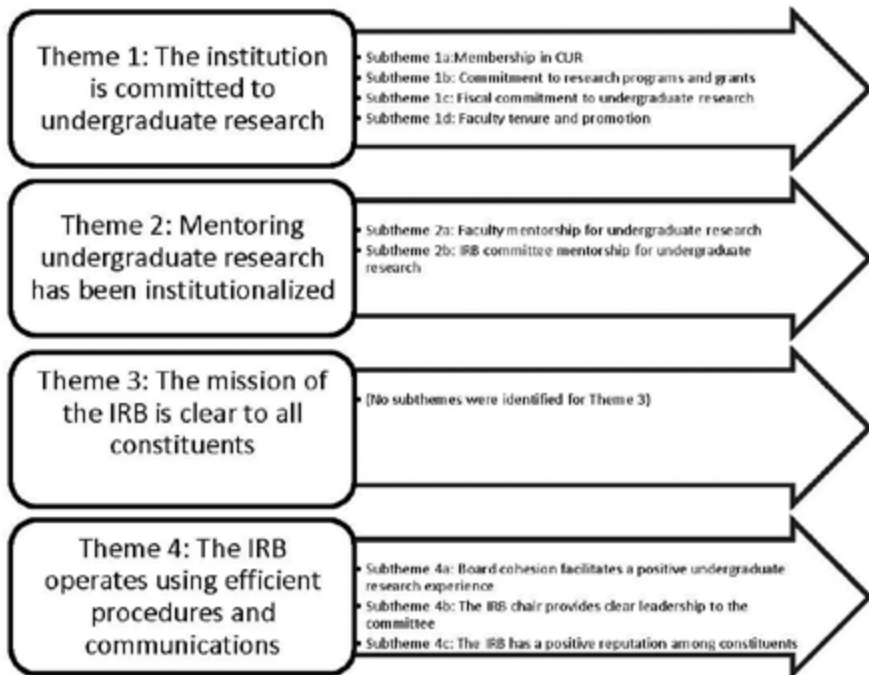


Figure 2. Figure 2 is a visual illustration of the findings broken down into themes and subthemes

Implications for federal public policy implementation

By and large, most public policy implementation theories were created during the 1970's and 1980's, over 40 years ago (Pulzl & Trieb, 2007) and may be viewed as not applicable or outdated. While Ripley created his General Model for Policy Process to be broad enough to apply to all stages of the policy process, it can also be applied specifically to any one stage of the process, in this case, the policy implementation stage.

Amidst numerous outdated implementation theories, lies a hybrid model for general policy process, that when applied specifically to the implementation stage, can inform and describe policy implementation (Ripley, 2010). The idea that the implementation of human subject research public policy is best done using a hybrid approach may be the most significant finding of the study. What is outlined in the federal code of regulations is the same for every institution, but every institution is using their own discretion, their own perceptions, their own environmental factors, and their own actors to implement this public policy in a slightly different way. Ripley was right to identify the four major components within his model (governmental policy activity,

social policy activity, policy actors, and environment), but what his model was missing, and what this study shows, is that the power of these components are not equal at the implementation stage.

The implementation of federal human subject research public policy at MRC occurred using a hybrid approach. While human subject research public policy was created using a top-down model from the Federal government, MRC chose to implement federal policy using a hybrid model of implementation that meets federal requirements, while capitalizing on the role the local actors can play in the implementation process. This model has resulted in a student- and faculty-friendly implementation emphasizing various learning outcomes and student mentoring, all while adhering to federal level requirements.

The findings of this case study are associated with various components of Ripley's model. I confirmed that policy actors at MRC, including the IRB members, and most notably the IRB chair, create and carry out policies in conjunction with the institution's mission and culture. MRC's policies and processes protect human subjects, but also protect the teaching and learning environment, and support undergraduate research and student learning. Environmental factors such as the institution's commitment to undergraduate research and the fact that mentoring undergraduate research at MRC has been institutionalized, has, and continues to, impact how the IRB (the actors) implement policies. According to Ripley's model (2010) the environment and the policy actors are intertwined with regards to policy implementation. They impact each other, and together, they impact both government and social policy activity. I found this to be true at MRC.

As the IRB members and chair, along with other key political actors, including faculty mentors, the administration, and the summer research program director, carry out the day-to-day decisions, it was clear they do so with best practices for undergraduate research and student learning in mind. For example, the summer research program committee rejects very few applications. On average, only 8% of first round applications were outright rejected, while 32% were sent back for revisions. Additionally, the summer research director personally calls or emails the faculty mentors of the students whose proposals need revisions, in order to communicate what is necessary for approval.

While the summer research program rejects only a small percentage of annual proposals, the IRB does not outright reject proposals at all. In fact, if an IRB proposal is not approved as is, the IRB chair personally calls the student researcher into their office and discusses what changes need to be made to move forward. The IRB chair also calls the faculty mentor to ensure they are aware of the necessary changes as well. It was evident during interviews that this personal approach to communicating necessary changes was both appreciated and valued by both students and faculty mentors. Every element of the research provided evidence that undergraduate research was woven into the fabric of MRC. In fact, the summer research director at MRC referred to undergraduate research as the institution's "stitch" and called undergraduate research an "institutional priority" (Personal communication, July 8, 2015).

While four main themes emerged from the research, it is important to note that these themes were not mutually exclusive. The implementation of IRB policy is intimately intertwined within the culture that is this undergraduate research focused institution. Many of the ways this college

is committed to undergraduate research and the protection of human subjects also help to institutionalize the idea of undergraduate research at the institution. For example, MRC has a day-long research symposium. This event not only shows the College's commitment to undergraduate research but institutionalizes undergraduate research at the College by having a dedicated day of no classes built into the academic calendar so student research can be highlighted.

Recommendations

Institutions that want to have rich undergraduate research experiences should adopt a hybrid approach to public policy implementation that ensures Federal public policy is being adhered to, but does so in a way that encourages and embraces student research. Although there is considerable literature and public discussion about the negative aspects of IRBs, if approached in a manner that embraces student learning, this study supports the notion that the IRB experience can be an extremely beneficial part of the institution's learning environment. Kuh (2008) listed undergraduate research as one of ten high-impact practices that benefit students. Research indicated positive undergraduate research experiences can impact retention in a very positive way (Ishiyama, 2001). The IRB process is a part of that high impact experience, thus institutions should be mindful of how human subject research public policy is being implemented.

I found Ripley's General Model for Policy Process applicable specifically to the implementation stage. Ripley's model was created for broad use and thus many would not consider using his model specifically for implementation. This is unfortunate because I found his model to be very adaptable, and his hybrid approach very informative to my research. Additional research to validate Ripley's model's applicability to public policy implementation analysis is strongly recommended.

Conclusions

Chadwick and Dunn (2000) sum up the last 50 years of IRB evolution by saying, "like many highway projects, the IRB system was sound when it was designed, but became out-of-date and overloaded almost from the start" (p. 21). IRBs are often viewed as authoritarian in nature and working against, instead of in collaboration with, the researcher. This was certainly not the case at this institution. MRC is an excellent example of a Council on Undergraduate Research institution that has overcome many of the negative stereotypes associated with IRBs. From a public policy theory standpoint, they have implemented federal human subject research public policy in a way that is institution-specific and student- and faculty-friendly. This College is an excellent example of what a "best practices" undergraduate research college is all about.

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Kristi N. Hottenstein, Ph.D.

Vice Chancellor for Enrollment Management

University of Michigan-Flint

3032 E. Kearsley St.

Flint, MI 48502

Tel: (810) 762-5723

Email: khottens@umflint.edu

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