Ethical research approval in a timely manner: IRB process flows and implications for redesigning them

by

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Abstract

Academic researchers have many complaints about the Institutional Review Board (IRB) at their institution, including the opaque decision making, the long wait times for decisions, and numerous other nuances unique to particular institutions. The IRB is a necessary entity to ensure that any research with human subjects at its institution is conducted ethically. Most researchers are not submitting applications for approval from the IRB often, and therefore the experience they have the first time is key to their perception of the value of the IRB, which in turn distracts from the goal of the IRB in the first place. This study sought to determine what aspects of the IRB process at institutions are pain points for researchers. After examining perceptions and experiences with IRB processes from 9 participants, findings showed that it is not necessarily long wait times or bad form design that make the process painful for researchers. Rather the user journey, as a whole, needs to be designed to minimize frustration and maximize confidence in their research. Recommendations for designing or redesigning the IRB submission process are discussed, which include design implications for an online submission tool.

Keywords: Institutional Review Board (IRB), ethical research, process design

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Chapter 1: Introduction

The Institutional Review Board (IRB) is an entity at an institution that is responsible for ensuring research being conducted at their institutions follow rigorous ethical research guidelines. This includes reviewing and assessing research according to the level of risk of harm associated with research prior to the research being conducted. The Common Rule, which was a result of a study on questionable and harmful research practices on humans used in the past, such as the Tuskeegee Experiments, outlines the basic ethical principles in research involving human subjects. All federal agencies that conduct research with human subjects adhere to the guidelines set forth in the Common Rule. Additionally, research institutions where research is being conducted with human subjects have adopted the guidelines. Such institutions, like universities, medical schools, and any institution that receives federal research funding, are permitted to implement the guidelines as they see fit for their institution. As a result, there is not a one-size-fits all approach to how IRBs operate. Instead, institutions are given much leeway in how they enforce the guidelines.

Submitting an application to the IRB for review is not an everyday task for most researchers. As such, each occurrence can inform or change their perception of the process for future submissions. Often researchers are dissatisfied with the process from beginning to end for various reasons; the time it takes for something to be approved; the application method itself; and the lack of transparency from the IRB in its decision making. This judgment clouds their experience with the IRB, which has a lasting effect on them and anyone they discuss the IRB submission process with, such as student researchers and new colleagues.

The original purpose of this study started with the intention of trying to solve one small element of the IRB submission process at institutions that require all applications to be on paper

with a wet signature in order to reduce the time that the manual process adds to the review period. During the course of the research, new federal Common Rule guidelines were proposed and adopted by research institutions. Additionally, the institution that was the focus of the digital signature research had adopted a new online submission tool in the meantime as well. As such, the study evolved to encompass the IRB submission process as a whole, which many institutions have already instituted as an all-online process.

This study examines the factors that elicit a positive or negative perception of the IRB and its processes, and the results establish a suggested framework for structuring the IRB process at an institution. The scope of this study is limited to IRB processes at academic institutions with research participants made up of IRB members and student and faculty researchers mainly in the social sciences.

Chapter 2: Literature Review

Background

Questionable research practices used in biomedical and behavioral research during the twentieth century, such as the Nuremberg Trials during World War II, and the US Public Health Service Syphilis Study at Tuskegee that was exposed in 1972, resulted in the need for a code of ethics to guide researchers in government and government-funded institutions. In 1974, the federal government adopted the Policies for Protection of Human Subjects as official government regulations (Smale, 2010).

Common Rule

In 1978, the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (The Commission) published the Belmont Report, which outlines the basic ethical principles in research involving human subjects (Bozeman & Hirsch, 2006). The ethical principles outlined in the report refer to the respect of persons, beneficence, and justice. According to The Commission, respect of persons includes consent requirements where the subject is "given the opportunity to choose what shall or shall not happen to them." The consent process contains three elements outlined in the report: provide the information, ensure subject comprehension, and base inclusion on voluntariness. Beneficence is explained as being transparent about the risks and benefits from participation with the goal of maximizing benefit and minimizing harm. Regarding the meaning of justice in this context, the report advises that research should not "unduly involve persons from groups unlikely to be among the beneficiaries of subsequent actions of the research" (National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 1979).

Since 1991, these principles are operationalized in the Code of Federal Regulations, Title 45 CFR Part 46, Protection of Human Subjects. Any and all federal government funded research must adhere to these regulations. Known as the Common Rule, the regulations mandate that institutions must have in place a committee of reviewers responsible for applying the regulations. Such committees, known as the Institutional Review Board (IRB), dictate that members are responsible for operationalizing the review of research and record-keeping. The Common Rule allows organizations to add additional IRB requirements at their discretion. As of today, 19 federal agencies adhere to 45 CFR 46, and most universities require IRB approval for any research involving human subjects, regardless of funding source (Office for Human Research Protections [OHRP-1], n.d).

In June of 2000, the Department of Health and Human Services (DHHS) created the Office for Human Research Protections (OHRP) to provide educational programs, oversight, and assurance of compliance with 45 CFR 46 (OHRP-2, n.d.). In January 2017, the OHRP revised the Common Rule, which had remained mostly unchanged since its inception (Murphy, 2017). The revision of the Common Rule was a contentious effort from the start, as many institutional administrators and researchers had strong opinions about the then-current policies and practices in place.

Known **"**vocal proponents of diminishing the role of IRBs" (Murphy, 2017), Shweder and Nesbitt, welcomed the revised Common Rule from 2017. In their view, "this long-sought and welcome reform of the regulations requiring administrative oversight… limits the scope of [the IRB] management by exempting low-risk research with human subjects from the board's review (Shweder & Nesbitt, 2017). Hatch (2018) summarized the changes, saying revised rules for exempt research **"**reduce burdens on research and universities, saving them time and

money… it allows them to get off the ground more quickly." Hatch reported that the new exemptions cover methods and data from oral histories, surveys, observations of public behavior, and the use of data that can't be tracked back to specific people (2018). These changes are particularly meaningful for researchers in the humanities, social sciences, and law, where such methods are the main source of data collection. In addition to allowing more research to be cleared as exempt, the revised rule also allows one IRB to cover multi-institution research, compared to the prior Common Rule which required any institution from any sector involved in a research study to get IRB approval from each of their home institutions.

Because the new Common Rule was not officially the law of the land until 2018, little data or literature exists that conveys any positive or negative effects on IRBs. Most of the literature about IRB processes and variations thereof was written prior to and up until the enactment of the revised Common Rule.

Perceptions of and Attitudes Toward IRBs and Their Processes

Much of the literature about IRBs and the way they operate portrayed the IRB in a negative light. Across higher education, in particular, IRBs are viewed as a hurdle that researchers do not look forward to dealing with, and, in most cases, there seems to be an adversarial relationship between researchers and the IRB. Hottenstein (2018) pointed out that IRBs "are not advisory boards. They are often viewed as authoritarian in nature and working against, instead of in collaboration with, the researcher." There are some common themes that came across in the literature that explain this phenomenon: variance in IRB processes, the perceived value of an IRB, a negative user experience on the part of the researcher/submitter and the reviewer/approver, and resistance to change in workflow.

Variance in IRB Processes Across Institutions

Bozeman and Hirsch (2006) pointed out that regulations regarding IRBs permit considerable latitude with respect to the membership and organizational structure of IRBs, but their duties and mission should be the same (p. 273). They went on to describe how the "flexibility of decentralization" of the IRB is a strength, and that "while not universally loved, the IRB is universally accepted" (p. 274). That sentiment was assumedly shared by many researchers, including colleagues of Aufderheide (2016). She reported that members of the IRB she served on at American University all said they "found serving on the board to be rewarding personally, and an opportunity to give… meaningful peer review." According to Labaree (2010), having an IRB approval is an "important ethical seal of approval," which, he said, improves the impression of a study's reliability and validity (p. 193).

Compared to positive views, there were many more examples in the literature of the negative criticism of IRBs among researchers and reviewers. Hottenstein (2018) summarizes the problems that variance in process creates, stating:

> *With over 10,000 IRBs nationwide and a vague set of federal regulations, interpretation of the regulations is not consistent. In addition to the sheer number of IRBs, consistency problems are compounded by the rotation and appointment of IRB members. (p. 37)*

Much of the literature homed in on the criticism of IRBs not being flexible enough for research in the humanities and social sciences (Hottenstein, 2018; Labaree, 2010)**.** According to Hottenstein (2018) historically, IRBs have been largely based on quantitative biomedical models, which does not comport with the nature of many research methods used in social science and humanities inquiry, which is largely qualitative. She argued that qualitative research

methodologies are “outside the IRB’s scope of knowledge, yet still within their scope of practice” (p. 31). Others agreed with this sentiment, noting the onus put on social scientists and researchers in the humanities, whom often use interactive and open-ended methods such as ethnography and interviewing, to provide research questions, questionnaires, and all other study materials to the IRB up front. “The construction of knowledge between the researcher and participants relies on developing a trusting relationship, a process that does not conform easily to predictable schedules and deadlines,” noted Labaree (2010, p. 191).

Risk inflation (Shore, 2009), is a concept that appeared often in the literature. Shore reports that risk inflation may be a result of IRB reviewers and possibly the review process itself using biomedical research as the standard (p.336), which mirrors the point that Hottenstein made regarding the makeup of the board itself (2018). She argued that IRB reviewers tend to inflate risk, “thinking in worst case scenarios, which then requires the researcher to identify contingency plans or strategies to prevent/minimize risks that were considered extremely unlikely” in the first place (p. 336). Regarding risk, in their case study involving the IRB process for multi-institution studies, Green, Lowery, Kowalski, and Wyszewianski (2006) took the stance that because IRBs are typically made up of “researchers and physicians who are biased towards quantitative research,” they cannot adequately review research in the social sciences, which leans more qualitative. They asserted that “IRB decisions may frequently be based more on institutional risk aversion” and that members “do not use a systematic way of assessing the risk/benefit ratio” (p. 215).

Members of IRBs also shared frustrations with the process (Aufderheide, 2016; Murphy, 2017). From interviews with IRB members from various institutions the following quotes

collected by Murphy shed light on the problems that IRB members (faculty, administrators, and outside members) face during the process. From an administrator/IRB member:

> *There is a lot at stake beyond assessing the potential risk to subjects. We try to be as flexible as we can, but institutionally you sort of arrive at what fits into minimal risk and create review processes accordingly*.

From a professor/IRB member:

> *It is a little more work, and some could find it onerous, but I still find it a worthy process because you get questions and suggestions that make you feel more confident that subjects are protected.*

From an outside IRB member:

> *There seems to be a major paradigm shift going on away from the original goal of the IRB to protect human subjects and toward the convenience of the researchers in the name of so-called efficiency. I find that of deep concern.*

Aufderheide (2016) stated that in order to not raise red flags, sometimes researchers will play down the risks that may be associated with their work. A colleague described why this is problematic:

> *This usually prompts the IRB members to 'fill in the blank' and come up with possible minor risks. This leads to back-and-forth with the researcher that is inevitably resolved positively but slows down the process.*

Perceived Value of IRBs

In the literature, the perceived value of the IRB process was questioned in different ways. In Spellecy and May's (2012) work, they were highly critical of IRB processes, describing them as "mystical" and "arbitrary" in nature (p. 991). They stated:

> The current IRB system is flawed at a very fundamental level. These flaws raise questions concerning the ability of the IRB review process to provide known, and viable, guidelines to researchers. This, we argue, undermines the normative legitimacy of the IRB process, calling for changes that revise how we conceptualize the IRB process. (p. 991)

In his review of Whitney, 2016, Schrag (2017) noted that "because IRBs can delay, restrict, or outright prohibit research, they wield immense power, enough to derail grants, projects, graduate degrees, and whole careers" (p. 434). Shore (2009) described how a negative faculty perception of the IRB leads to a perpetual cycle of doubt among students. "Instructors may relay negative perceptions or intimidation to their students… Some instructors may present the IRB as 'bureaucratic in nature,' potentially implying that the review process does not contribute to the ethical conduct of research" (p. 335).

Negative User Experience

Negative experiences with the IRB color researchers' view when submitting future protocols. There are several instances in the literature where an overall bad user experience, from the process of submitting a protocol to eventually getting denied or approved, furthers the notion among some in academia that the IRB should be looked upon as a hassle, rather than a necessary step to ensure ethical conduct.

Shore (2009), in her assessment of working with the IRB on behalf of student researchers, conveyed that IRB resources, including access to IRB staff, is wholly inadequate. She mentioned the "inadequate written materials aimed at facilitating the completion of IRB materials" as a particular hindrance (p. 335). She also expressed qualms with the time-consuming nature of the IRB process, indicating that when students do not factor in enough time

from submitting an IRB to possibly receiving feedback or an outright denial on their first try, it is challenging because professors usually expect students to complete a research project in one semester (p. 335).

Aufderheide (2016) and her fellow reviewers expressed that a major reason that IRB approval gets slowed down is simply people not reading directions. If the tables were turned, one might wonder, is it possible that the directions are not easily interpreted? In their case study describing their IRB transformation at University of Houston, Liberale and Kovach (2017) described how dissatisfaction among researchers was often long delays in the process. They noted that the "items [that] represent the failures with the highest risk of causing delays within the IRB review process… include 1) [a] missing cover sheet and 2) not enough time for IRB process administrators to conduct protocol pre-review" (p. 43). One wonders in such cases, could ancillary documentation, such as the cover sheet, which explains revision history, be slowing down the administrators?

As mentioned previously, inconsistency in the IRB process is cited as a main frustration in the literature. By design, IRBs are self-governing, and the makeup of the board "often takes on the distinct culture of the institution it serves, leading to variations in application procedures and in how volunteer reviewers interpret the regulations" (Labaree, 2010). As such, what might pass through as exempt at one institution, or even in one segment of an institution in the case of universities that have multiple IRBs in multiple divisions, might require full review at another.

Labaree (2010) pointed out that even though IRBs have much autonomy, there are still federal guardrails in place that prevent reviews from being done over email or by proxy (p. 191). In fact, in an early draft of the revised Common Rule in 2017, use of an online tool was proposed

as a way to facilitate easy decisions for research regarding whether their research was exempt. The tool did not make it into the final rule (Murphy, 2017).

The case study referenced earlier by Green et. al. (2006) revealed failures in the IRB process, notably long turnaround times, lost paperwork, difficulty in obtaining necessary forms, and unavailability of key personnel at IRB meetings to be detrimental to submitters' ability to conduct research. For a multi-site study that involved academic institutions as well as a large government agency, they observed that although there were "no qualitative differences in procedures or requirements" (p. 226) at either type of site, IRB approval took anywhere from 52 days to 798 days for approval at each site (p. 215).

Chapter 3: Methodology

Design

Selection of Methods

Phase one: Usability testing. In 2014, a semester-long design studio at the University of Baltimore (UB) enabled two students, one of which was this author, and an advisor to research, design, and usability test a method to collect electronic signatures on IRB approvals. UB had used a paper system for applications and approvals, which required wet ink signatures from all parties involved in the process. The paper is kept on campus in an IRB Coordinator's office in file cabinets. After doing stakeholder interviews, the researchers ended up designing a portal that would make the entire IRB submission process electronic, including signatures.

Phase two: User interviews. User interviews were conducted to gain insight into the variety of IRB application processes at different institutions. The interviews were conducted in 2018 and 2019 with participants at institutions that vary in enrollment size and geographic location. The interviews were conducted to gain insight into the variety of IRB application processes at different institutions. Enrollment totals were as low as 4,500 and as high as 50,000. Interview topics were centered around the participants association and familiarity with their institutions IRB and the IRB submission and approval process. Participants were probed to express their impression of their IRB process as well as of the value of the IRB itself. Additionally, participants were probed on their knowledge of the Common Rule and any implications it has or will have on their future research. All participants used an electronic submission system with the exception of three users whom were still submitting and reviewing

paper applications. These users were at an institution that was beginning to pilot an electronic submission system at the time of the interviews.

Online tool walkthroughs. Tool walkthroughs were conducted to gather information pertinent to the design and functionality of various online IRB application tools. Four of the interviewees conducted a walkthrough of their institutions online IRB submission and approval tool.

Data Collection

Design Studio paper prototype tests were conducted in person in the Whimsy Lab on the University of Baltimore campus. Two digital prototype tests were conducted in person and the other was conducted using Zoom. None of the tests were recorded. A lab report was produced at the end of the project (Owens, Locke, & Walsh, 2014). See Appendix for lab report. An IRB application for the projects was submitted on behalf of the student researchers by the advisor.

Interviewees and walkthrough participants completed an intake questionnaire and an online consent form via Google Form. Interviews and walkthroughs were conducted via Zoom video recording application. Recorded audio was transcribed with a transcription service. See Appendix for participant consent form, participant intake survey, and IRB approval letter.

The synthesized data collected from the design studio and interviews informed the different recommendations and implications for redesigning the IRB application process.

Phase One: Usability Testing

Participants

Six participants were included in the testing of the two prototypes. Three participants were shown the paper prototype, and three were shown the digital prototype. One participant was

shown both prototypes on different occasions. Participants were an even mix of UB graduate students and faculty, and the IRB coordinator.

Materials

Prototypes. A paper prototype was created using pencil on 8x11" copy paper and index cards. Interactions were built into the paper prototype for the tasks of adding attachments and a digital signature. The digital prototype, created with Axure RP, was built to include an informative and interactive dashboard (see Figure 1), as well as a self-guided application process and a guided walkthrough, or wizard, for creating a new IRB submission (see Figure 2). Interactions were built into the prototype for creating and/or reviewing a new IRB application (see Figure 3), viewing various modals, including adding a digital signature, approving submissions, attaching documents (see Figure 4), writing messages and viewing application statuses.

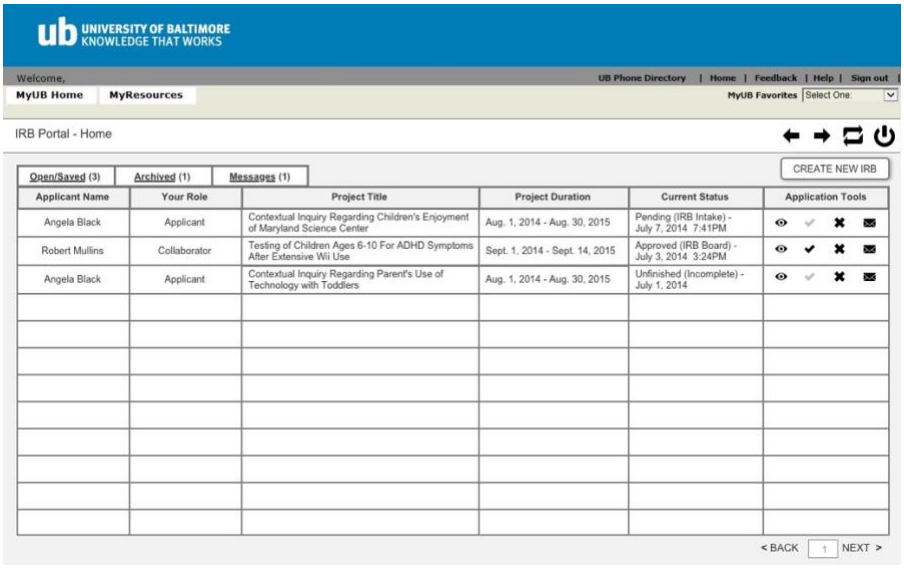

Figure 1. Prototype dashboard screen.

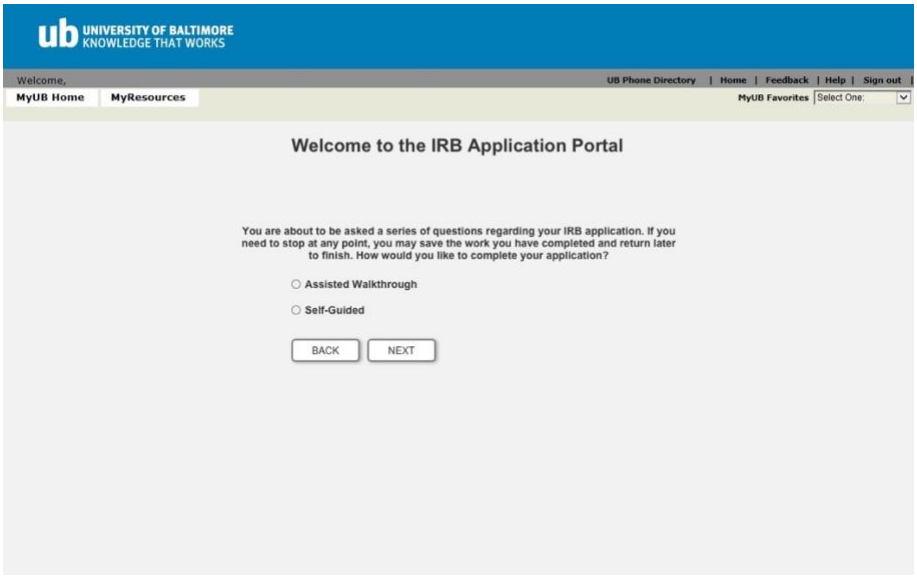

Figure 2. Prototype assisted walkthrough or self-guided choice screen.

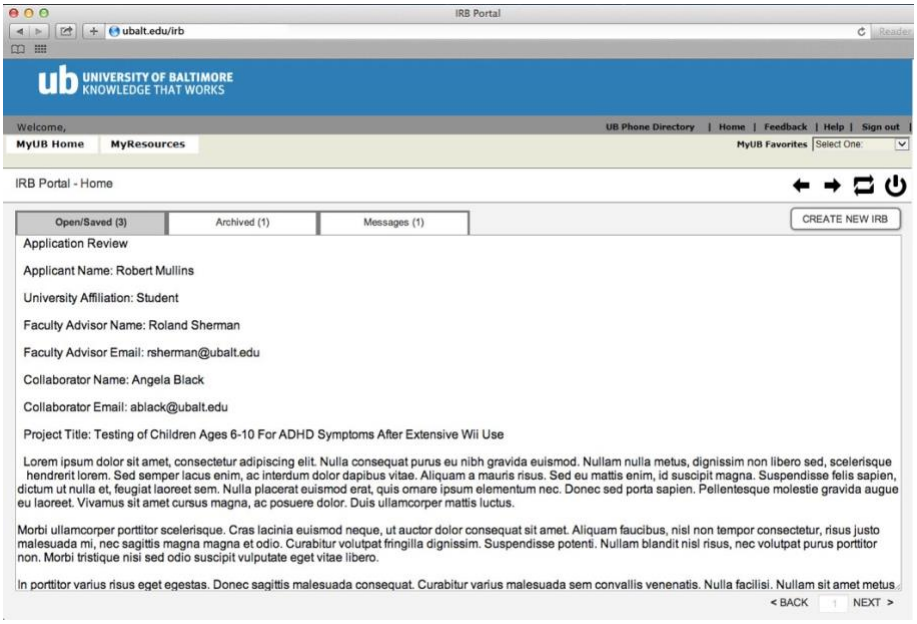

Figure 3. Prototype review submission screen.

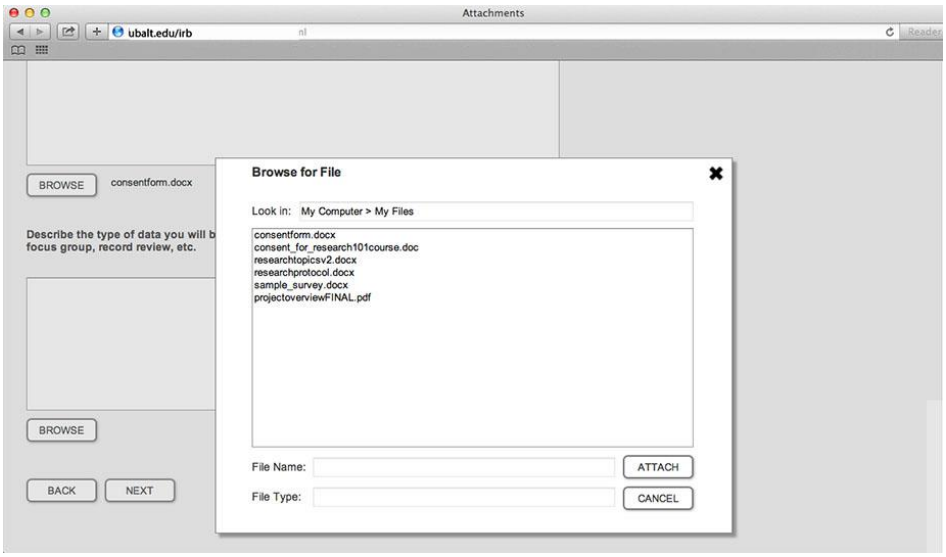

Figure 4. Prototype add attachment modal.

Procedures

This project involved interviewing stakeholders, including the IRB coordinator to assess the then-current state of the IRB process. After gathering requirements, the researchers created a paper prototype and conducted usability testing on it with users with different experience levels with existing IRB processes, including students and faculty researchers. After synthesizing feedback from the paper version, a digital version was created using Axure, which was then usability tested with users. The tasks completed by participants on both prototypes were to create a new application as a researcher/submitter via the self-guided method, attach files, sign, send a message, and review submission details.

Data Analysis

An iterative approach was taken during each testing phase. Based upon gathered feedback during a session, modifications to the prototypes occurred and were then validated with

the next participant. By the end of the testing phase a few more minor adjustments were made culminating in a final design.

Phase Two: User Interviews

Participants

Interviews were conducted in 2018 and 2019 with nine participants from four different institutions with various enrollment sizes (see Table 1):

Table 1

Participant Demographics

	Sex	Institutional role and association with IRB	Institutional enrollment	Institution has medical school	Has served on IRB
P-1	F	IRB Coordinator	4,500	No	Non-voting member
P-2	F	Full-time social science faculty researcher/submitter	4,500	No	Yes
P-3	F	Outside community member of IRB/approver	4,500	No	Yes
P-4	M	IRB member/approver	4,500	No	Yes
P-5	F	Full-time clinical researcher/submitter	21,000	Yes	No
P-6	F	Full-time social science faculty researcher/submitter	50,000	Yes	No
P-7	F	Full-time social science graduate student/submitter	50,000	Yes	No
P-8	M	Full-time social science graduate student/submitter	44,000	Yes	No
P-9	F	Part-time social science graduate student/submitter	4,500	No	No

Procedures

After obtaining informed consent from participants, one-hour user interviews were conducted via Zoom, a video chat application. The interviewees who are submitters of IRB applications were asked to discuss an applicable range of topics including; their area of study; their experience with the IRB and its application process; the IRB application process at their institution; their familiarity with the Common Rule and ethical implications associated with IRB protocols; specific positive and/or negative experiences during the application process; and ideas for improving the experience.

Online tool walkthroughs. Walkthroughs of tools occurred at the end of the interviews on Zoom using screenshare. Discussion topics included the different features and functionality, as well as how to create and check the status of an IRB application submission. All walkthroughs were conducted with researchers that submit applications.

Data Analysis

After all interviews were completed, affinity mapping was utilized to group feedback into themes. After synthesizing the response data from the walkthroughs, additional design implications were identified.

Chapter 4: Results

Phase One: Usability Study

Prototype testing

The evolution of the paper prototype to the final digital prototype was the result of feedback received and iterative design over the course of the study.

Paper prototype. Results from the paper prototype tests indicated that users were in general pleased with the idea of an online submission system, first and foremost. They also provided critical feedback that would be implemented in subsequent iterations.

Terminology and copy. Since the paper prototype included language directly from the existing paper application form, some of that language continued to confuse users. The term "deception" was pointed to many times as one that users found confusing. Users also needed clarification about the question related to needing agency head approval. Users commented on the redundancy of questions asked. Some questions were perceived to be the same question, just asked in a different way, so the question was why a user would have to enter the information twice. User feedback about wording such as this led to the inclusion of tool tips and/or clarifying instructions in the prototype, as well as solving the issue of perceived redundancy in the form.

Number of screens. Users commented that navigation through the prototype included too many screens. Many parts of the application require redundant information, so they wanted to see as much similar information on one page as possible. This would be solved for in the digital prototype.

Attachments. The process for adding an attachment to an application caused confusion. The interaction was sound; however, users expected confirmation that a file was successfully uploaded and attached. This was added in a subsequent iteration.

Status. Users expected the tool to provide a way to see an application status, that would include the estimated time for processing and whether an application has moved into expedited or full review status. This would be solved for in the digital prototype.

Digital prototype. Feedback from the paper prototype phase informed the design of the digital prototype. Any new feedback received during digital prototype testing was incorporated iteratively throughout the testing phase.

Terminology and copy. Terminology and instructional text were simplified as much as possible throughout the prototype, however there was still some confusion. For one question, the term "behavior" was pointed out as a "subjective term," therefore a user was unsure how to proceed with answering the question. Users continued to comment on the redundancy of similar questions. At that time, the project team did not have full understanding of which questions could be removed or consolidated further, according to UB IRB policy.

Number of screens. The digital prototype pared down the number of pages in the application by combining similar questions onto one page, thus reducing the amount of times a user would have to select "Yes" or "No" radio buttons and the amount of times a user would have to click "Next.." While this consolidation added more scrolling interaction to the page, users were not concerned by this additional scrolling.

Attachments. All questions related to attachments were incorporated into one page. Attaching multiple files requires repeating the same interaction multiple times, so consolidating these interactions into one part of the application helped streamline the process. To take this solution a step further, a bulk upload option would be optimal for this process. Since the questions with an attachment option also include a long-form text box option, a user was not certain whether they would need to use plain text in the box, or if they had to input text into the

box as well as attach a document. Copy with clearer instructions would help alleviate this confusion.

Phase Two: User Interviews

Perceptions

Value of IRB(s). Participants most often described their institutions IRB as having value; however, there are many stipulations associated with this opinion. The participants that were board members themselves push the value of the process as providing needed oversight. These participants believe that the ethical implications of breaking IRB protocol outweigh any particular grief one may experience in the interaction with the board. While IRB members had a positive perception of their role, they admitted the IRB is not perfect. Researchers, on the other hand, generally did not convey positive perceptions of the IRB process.

Positive perception. A board member viewed their role on the board as a way to provide guidance, or learning experience, to students.

> *I enjoy working with students… A lot of the proposals that come through the IRB, I didn't know this when I joined but it's like a perk for me, do come from students, so I think part of my role as an IRB member is to help students through the process and offer the kind of comments and feedback that will be valuable to them (P-3).*

The makeup of the board is advantageous for some. One participant pointed this out when describing the institution's board membership, which includes faculty from their program on the board as the chair.

> *The constitution of the IRB is important, and I think [my institution] does a good job… [of] trying to have a faculty member from our division be on the board. [It's] critical for continuing to do as much research as we do (P-2).*

A participant explained that at a previous institution where they did research, the university and its programs were focused on their area of study. In their opinion the IRB had a better understanding of the research and therefor the review and approval process was not seen as particularly stressful or burdensome (P-7).

Negative perception based on negative experience(s). All participants voiced frustration with the process in some way. One participant described the IRB as "a self-governing republic… having a reputation for being bureaucratic" (P-8). Another participant, a board member, admitted that the IRB requires researchers to sometimes go through "unnecessary bureaucratic obstacles" and said the board's "grip may be too tight" (P-4). These ideas were woven throughout the responses from participants.

For most, the application processes and procedures themselves have instilled a sense of animosity toward the IRB. As Shore (2009) described in the literature, one negative experience can leave a lasting impression among researchers. Moreoever, faculty researchers can also instill that negative impression in their students.

> *I have a graduate student… I had to submit for her. She's been very lucky that she hasn't had to deal with anything yet… but I'm sure in the future she'll get her own terrible experience (P-6).*

One participant got pushback on an application that was submitted on behalf of a class of students. They described the occasion as a "teachable moment" for the students.

> *[The students] do get frustrated. I shared the email and the list of concerns that were forwarded to me by the IRB… I showed them how I responded so that they could just see that it's an imperfect process… they were frustrated by [the fact that] the best guidance that could have been given to them by their faculty member was not correct… And I expressed my frustration too. But students realize that potentially from board to board, from reviewer to reviewer, there's potential inconsistency (P-2).*

These implicit or unconscious biases, one could argue, might color a student's view of the board from then on. Whether said out loud or not, the impression is still communicated.

Objectivity of the board was questioned by some researchers. One participant knew the board membership at the time of submitting an application and believes a member's lack of objectivity led to a difficult approval.

> *I've had ones where they've written me back [and said] … 'this isn't human subjects research because you're not contributing to knowledge.' It [was] because the person is a quantification scholar and [this] study was interview based. They said, 'What is this? This isn't human subjects research' (P-6).*

One participant researching issues related to drug use battled the IRB for six months before getting a study approved. The participant chalked this up to differences in ideologies.

> *There was a lot of ideology that got in the way… the first time around it just felt like there were some people who had a big problem with it and they were going to*

> *look for every detail that they could to try to say 'this is why this shouldn't be done' (P-6).*

Another theme that stood out as participants described their interactions with the IRB was overreach.

> *There have been a couple of proposals that have bounced back at me for things that are unrelated to ethics. ...people shouldn't be able to bounce back an IRB [application] unless they can clearly explicate 'this part of the code is what you're violating' (P-2).*

In the literature, Hottenstein (2018) described ways that the everchanging makeup and voluntary nature of the board leads to inconsistency in what may get approved at any given time. A participant described how this seemingly affects the IRB's motivation, leading to a perception of overreach.

> *That's where the overreach can come in… there was a chair of the IRB that was an attorney and there was at least one other member of the IRB who was an attorney. They continually… conceptualized the role of the IRB with an eye toward the fact that they were lawyers. And they kept talking about 'Well, then we wouldn't need to worry about litigation from this.' That's not the point (P-2).*

> *[The IRB needs] somebody in charge who continuously reminds the committee that their charge is to ensure that the protocols adhere to ethical standards and don't go beyond that (P-2).*

One participant involved in a longitudinal study at a clinical research institution described their perception of how their institution's board views "external IRBs," or IRB applications covering research at multiple institutions under one IRB approval.

> *They don't like it… [The IRB] does not like external IRBs because they can't keep track of what you're doing, who you're consenting, are you doing it right… so you have to justify to the IRB that you can use external IRB… they don't like it here. I had to fight for the two that I have (P-5).*

On the subject of submitting an "umbrella IRB," or an IRB application on behalf of a class of undergraduate students conducting research for a class project, one researcher explained that the reason the students do not submit on their own behalf at their institution.

> *The reason we stopped [having the students submit their own] and we're taking a different approach is because I was told by the IRB that it was too onerous. They were getting too many proposals. And we're trying to do a cost-benefit analysis of what the students can get out of it but also be conscious of the fact that we need them to get their stuff done in a semester (P-2).*

The participating outside/community IRB member generalized their negative experience with faculty submissions.

> *On occasion, there are faculty proposals that are awful… you think, 'You know, this person is a faculty member at a university, and they should know better'…*

> *[it's] jargon filled or extremely poorly written, in a way that suggests they really don't take the process seriously (P-3).*

Process

Participants submitted IRB applications in one of two ways: using a mostly offline method of a Microsoft Word document via email (offline), or via an online submission tool (online). As mentioned previously, the participants' judgement of the process at their institution is often clouded by their previous interactions and experiences with the IRB. There was no correlation between the method of application (email or online tool) and satisfaction with the process. The time from the start of an application through being approved was generally seen as reasonable, although plenty of anecdotes related to review time and communication with the IRB contribute to the view that the process has major pain points. The email method falters most when inboxes aren't monitored closely. Online submission tools reportedly streamline the process; however, they still have shortcomings according to participants.

Timeliness. All but one participant knew the general guidelines of how long their IRB indicates an application should take to be approved, and in those cases the guideline was two weeks for exempt research, three weeks for expedited research, and one month for full board review. None of the participants were aware of how the guidelines were formed; whether by the mandated Common Rule or by the IRB at their institution themselves. Many researchers indicated that one or more of their applications did not fall within those guidelines, which was vexing for them.

> *[My institution] has a reputation for being a bureaucratic [expletive]. [I had one] take three months… it wasn't exactly a linear process. At another institution [another application] was shockingly fast… a month and a half (P-8).*

One participant that was currently in the application process at the time of the interview relied heavily on their advisor to navigate them through the email-based IRB application and approval process.

> *I submitted probably a month ago and got it back this past week. [My advisor and I] made the changes and I submitted it back… How long should I wait? Next week I'll just ask [my advisor] 'Alright, how long should this take?' (P-9).*

Participants reported full board reviews for their research taking anywhere from one month up to eight months.

The board member participants, as well as the coordinator participant, are associated with the same institution and described the time the email-based process at their institution takes based on how they review and respond to submissions.

> *Sometimes there's a lot of going back-and-forth… The simplest ones [to review] I don't think it could possibly take less than about half an hour… One to two hours is reasonable… about 50% of them are fine, 25% need follow-up but I don't need to see it again, and then 25% I do need to see again (P-3).*

> *It's very rare that I provide approval or recommendation to approve with no commentary… about 50% of the time there's more information needed (P-4).*

There [is] no real difference between expedited and exempt. It [is] treated exactly the same… it [goes] out to two reviewers. Exempt wasn't any shorter in terms of review time as compared to expedited. That was always kind of strange to me, that there was just no real difference other than the label it got at the end (P-4).

I look at [your application] and [if] it's incomplete I have to tell you no, I can't submit it two people right now. I have to send it back to you and then you have to send it back to me… Then I send it to two board members… I have to wait for both of them to [respond]. I can say in the email, 'please review by so-and-so date… What holds it up having to go back-and-forth via email… [The reviewers] are very dedicated but sometimes it takes a little bit longer… [the email] gets stuck down in a bunch of other emails they receive (P-1).

IRB board members are not paid to do this… during the summertime it's hard to get ahold of everyone… Everything [takes] a bit longer to get approved (P-1).

Submission and review. For the remaining portions of these results, participants are referred to as "users" while describing their experience of using different methods for submitting IRB applications. As previously indicated, the submission method will be referred to as "offline," the manual process for completing a Microsoft Word document or Adobe PDF and using email to submit an application, or "online," the process of submitting using a cloud-based

web application. Five users submit via the offline method and four use the online method (See Table 2).

Table 2

IRB Application Submission Method by Participant

	User type	Submission/review method
P-1	IRB Coordinator/approver	Administrative
P-2	Faculty researcher/submitter	Offline
P-3	IRB member/approver	Offline
P-4	IRB member/approver	Offline
P-5	Researcher/submitter	Online
P-6	Faculty researcher/submitter	Online
P-7	Student/submitter	Online
P-8	Student/submitter	Offline
P-9	Student/submitter	Offline

Note. Users P-1, P-2, P-3, P-4, and P-9 represent the same institution. At the time of this research the institution was undergoing a transition from an offline method to an online method. Three of the users had exposure to the online tool as part of a pilot program at the university; P-1 had accessed the tool in an administrative capacity, P-4 had reviewed one application but used the offline method in all other cases, and P-9 had not officially submitted using the tool so they demonstrated submitting a new application using the tool for the first time. P-2 and P-3 had not been exposed to the online tool.

Offline user experience

The offline submitter complained of the application being confusing and redundant. No matter how many times they had completed the form in Word, they still had questions each time that they did not know how to answer.

> *The language in the code is awkward. I've been doing research for twenty years but there's one section of the IRB that I can almost never figure out what I'm supposed to check (P-2).*

This user indicated that a simple decision tree for the application questions would streamline the process.

One offline reviewer described how they will often review submissions and have questions that aren't answered in the application form, but they are answered in the consent form. The user's main complaint is that the application form and the consent form don't "agree with each other," which requires excessive back-and-forth between the reviewer and submitter.

> *There could be a lot more online education, like as you're going along [the Word form], if you hover over something or click on something… [there] could be a pop-up or something that helps you… [and] on the consent form, 'Don't forget that this has to agree with question 3B on your application.' (P-3).*

Regarding the back-and-forth, this is a pain point in many of the offline users' experiences. The main reason for this is that submitters and reviewers rely on email for all communication with the coordinator during the process. Emails can easily get deleted unintentionally, but most users referred to "losing" the email in their inbox, where there is just too much to read.

> *I think the back-and-forth, during periods when it's busy… it back[s] up a little bit. You might have three of four of them going at a time… I search my email inbox for that unique little number… I really think that is the most tedious (P-3).*

When an application is submitted, the user is required to provide a wet signature. Similarly, when a submission is approved, the IRB coordinator must get the signature of the IRB chair before sending the formal approval letter. This adds unnecessary processing time. The offline users deal with this in different ways: One user took a picture of their signature on their phone and emailed it to themselves. They then inserted the image of the signature into the Word document. Another would print the application, sign and scan it, and email it. When the IRB coordinator gets a signature from the chair, they get the wet signature on letterhead, scan the letter, then email the letter to the applicant.

> *I'm not opposed to digital signatures. I think we have to adapt to the times, and I think a digital signature is every bit as competent as compared to a wet signature, if not more (P-4).*

In one user's case, they were required to route hard copies of the forms for review.

> *I was literally putting [the documents] in a box… I printed them out, I signed them, I left them in my advisor's box (P-8).*

Online user experience

The tools reported on in this research are Kuali Protocols, Point, and eBoard[1]. Point and eBoard appear almost identical, save for the colors and styles used for each. It is safe to assume these two systems are licensed third-party software. For privacy and confidentiality reasons, depictions of real screenshots of Point and eBoard are included in these results. Screenshots of

[1] Some names of tools (Point and eBoard) have been changed to protect anonymity.

Kuali have identifying information obscured. All tool features and designs are reported on based on what could be seen on the screen during the tool walkthrough or by description from the user. The tool used by the university undergoing a transition from offline to online, Kuali, is licensed third-party software. See Table 3 for a breakdown of the features of online tools as reported by users at the time of this research.

Table 3

Tool Features as Reported by User(s)

Feature	User(s)
Requires VPN connection	P-5
Dashboard	All users
Templates for specific types of research	P-5, P-6, P-7
Decision tree application flow	All users
Suggested word counts in text boxes	All users
Upload/add attachments	All users
Application status display	All users
Commenting	All users
Track changes	P-5, P-6, P-7
Duplicate or copy an existing application	P-6, P-7
Electronic signature enabled	P-5, P-6, P-7
Messaging between submitter/coordinator & coordinator/reviewer	All users
Approval letter template	No users

Status of ongoing study display	All users
Notification of upcoming renewal	P-5, P-6, P-7
Notifications trigger email	All users

Note. Users P-1, P-2, P-3, P-4, and P-9 represent the same institution. At the time of this research the university was undergoing a transition from an offline to an online method. Three of the users had exposure to the online tool as part of a pilot program at the university; P-1 had accessed the tool in an administrative capacity, P-4 had reviewed one application but used the offline method in all other cases, and P-9 had not officially submitted via the tool so they demonstrated starting a new submission using the tool for the first time. P-2 and P-3 had not been exposed to the online tool. Users P-6 and P-7 represent the same institution.

None of the users were in the process of submitting at the time of this research, but they were able to demonstrate how to start an application, as well as open and review a past application, therefore the usability of the tools was mostly unremarkable, with the exception of Kuali, which will be detailed later in the results. Point and eBoard users were familiar with how to complete tasks to submit an application. They did not indicate that learning how to use the tool was particularly difficult, and some indicated that the IRB's website often answered many questions they had. They did not have to complete any sort of training before using the tool, and they indicated they learned while doing their first application.

> *No, I did not see a tutorial or instructions, and if there was, I didn't see it… I just kind of went in and figured it out (P-6).*

Advantages over paper. After accessing the tool via the user's institutional student or faculty portal, each tool opened to a dashboard, which provides a clear snapshot of application statuses. The link to create a new application is on the dashboard. Signatures were handled completely electronically.

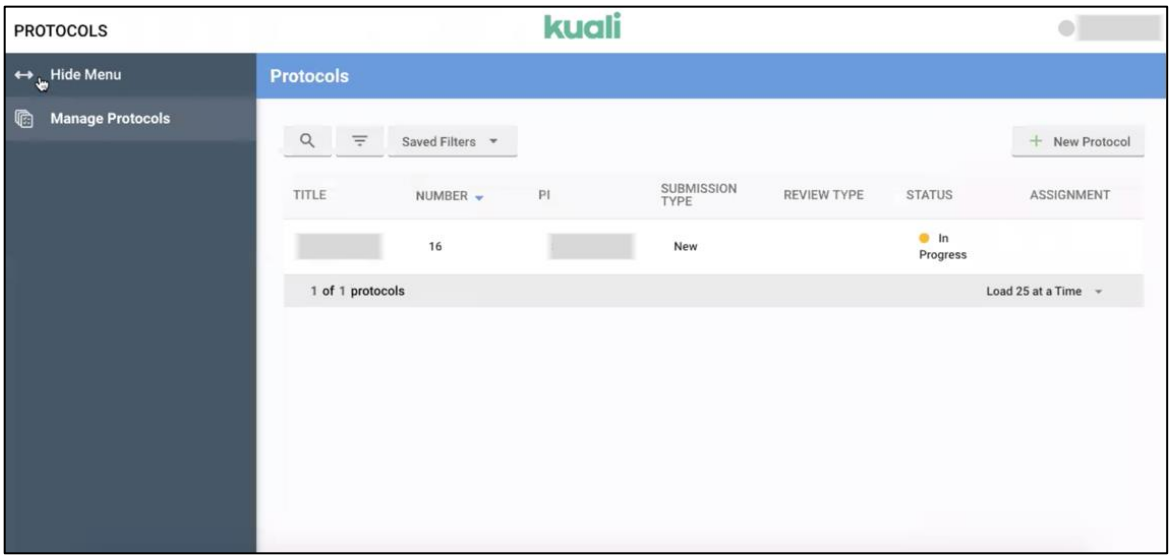

Figure 5. Kuali dashboard.

Figure 6. eBoard dashboard.

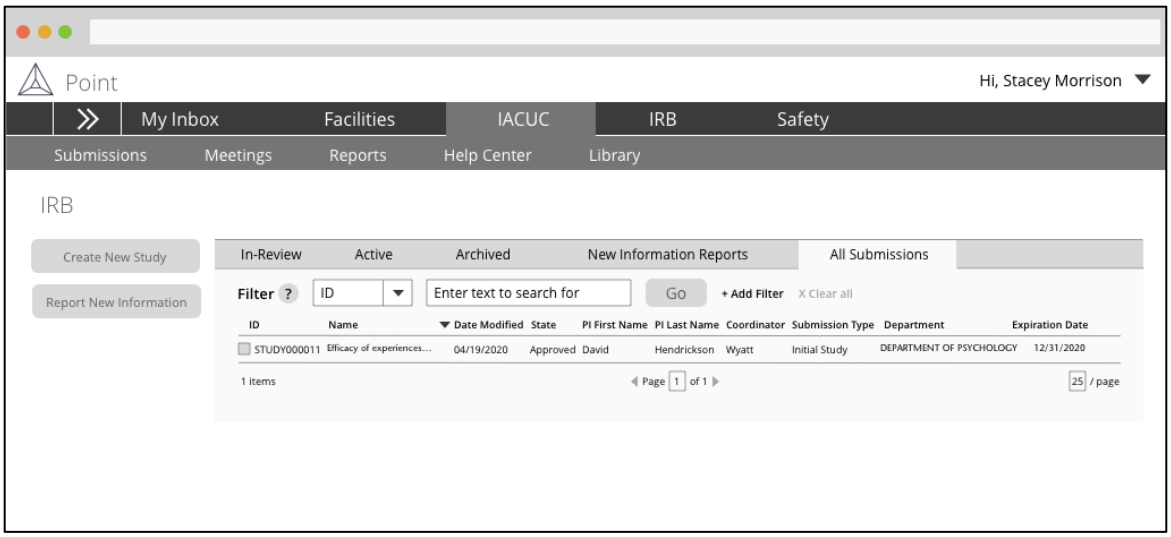

Figure 7. Point dashboard.

Streamlined application. For new submissions, Point and eBoard both have a feature that allows a user to select a template for the type of research they are doing, which only includes fields relevant to that type of study. The template functionality eliminated guess work and allowed users to reportedly complete an application in anywhere from fifteen to thirty minutes. Once started, the application user interface on all three tools featured a checklist as a progression indicator.

> *There weren't as many redundancies with [Point]. It eliminated a lot of having to repeat the same stuff over and over again… It was a lot easier to find the forms [I] needed… It was easier to skip and see, 'Okay, I need to go to this section, now I need to fill out this form.' (P-6).*

> *There are templates for everything. That's one thing that we don't have to think about. You just find what kind of study you want, pull out that template protocol, and then there's consent templates, and you just fill in what you need (P-5).*

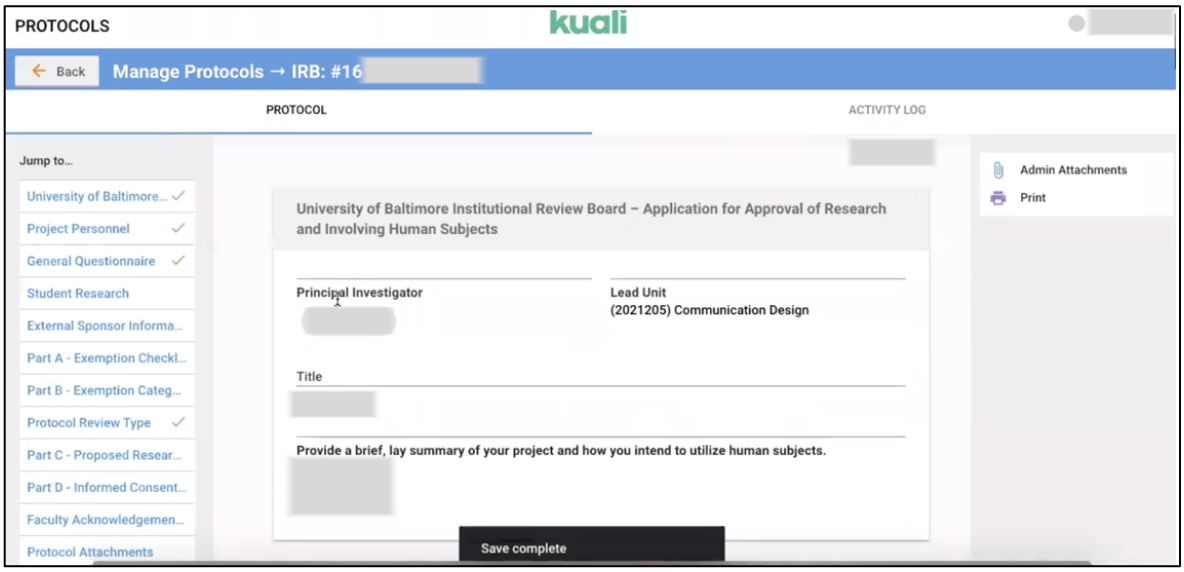

Figure 8. New Kuali submission form with checklist.

Status changes. Users of Point and eBoard like the feature that shows and tells them where their application is in the review process. Those tools provide very detailed information about who has done what activity with the application, where it's been routed, if changes are necessary, and other similarly useful data.

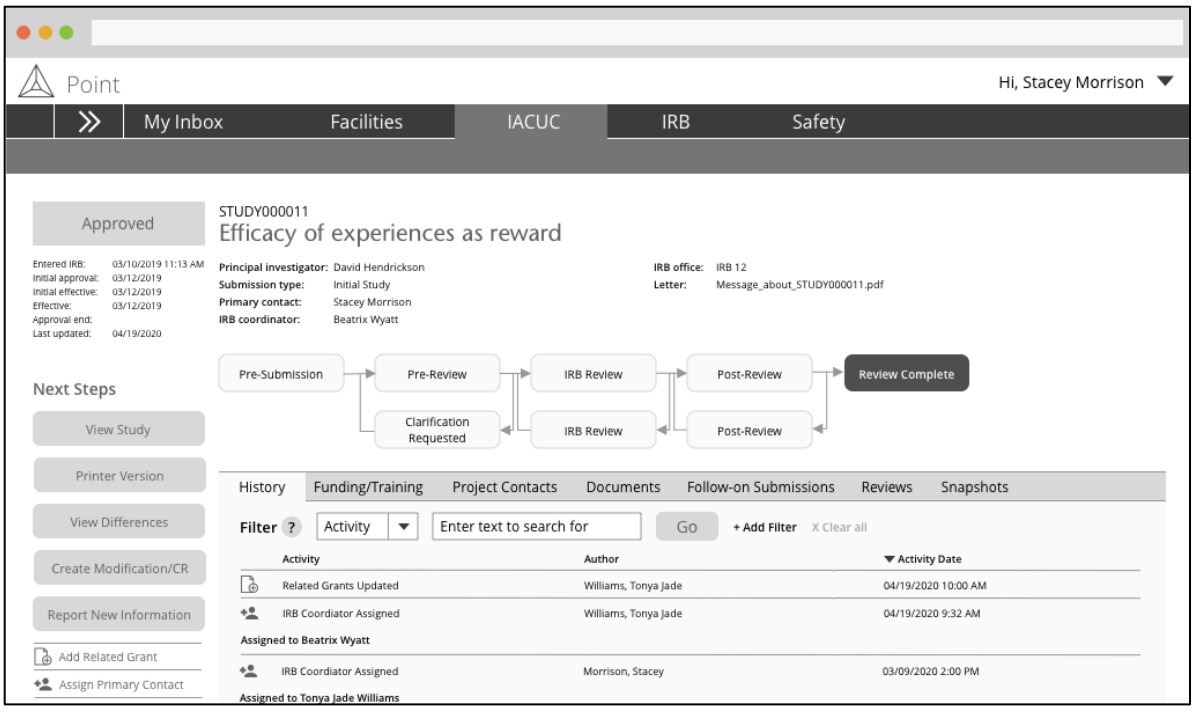

Figure 9. Point status indicator.

Users were not impressed by the visualization of the status indicator, however.

> *I would love a visual timeline where you could see… the same way you watch a package being delivered from Amazon; now it's in the hands of the reviewer. Now it's been returned back (P-9).*

If a document requires changes or follow-up on items, the user is notified via email. Once logged in, not only can they see the requested changes or questions and who entered them, but the comments appear in-line with the text of their application, so it is easy to determine where to make the change or modify the information. Once the changes are saved and the application routed back to the reviewer, the reviewer is able to see tracked changes to compare the prior version to the updated version. Users are alerted in the tool and also notified via email when a study is coming up for renewal or recertification.

Electronic signatures. Most of the online tools used some electronic mechanism for "signing" completed applications and approved submissions. In fact, no signatures were required at all; the student or faculty identification number acted as the signature with a time stamp. Users indicated that the approval came in the form of an email, which did not include a wet signature or any other type of identification of who the reviewer or signee was. At the time of this research, the university transitioning from offline to online had not adopted an electronic solution for signing approved submissions. The coordinator still printed out the approval letter, obtained a wet signature, then scanned the document and attached it to an email.

Underutilization. There were several features of the different tools that were not utilized at all and when asked the users could not explain what the feature was or who would use it. Some functions were not labeled intuitively, which may have led to users ignoring features. In Point and eIRB, these included My Inbox, Meetings, and Reports.

Online pain points. The bulk of the frustrations pointed out during the walkthroughs weren't necessarily about the tools themselves, rather they were usually in reference to the steps the user takes to begin using the tool and to the follow-up process after an application had been submitted. For example, three users indicated that they were required to be connected to the university's virtual private network (VPN) in order to access the online tool, something that was a pain point for the users. Two of those users indicated that the policy at their university had recently changed and VPN connection was no longer required, which they were pleased about.

Some users lamented the perceived lack of notifications they get via email, however those users indicated it is possible they are receiving emails, they just don't pay attention to them or "lose" them. One user has learned to expect a delay from when their application has activity or the status has changed, to when the notification comes through email.

> *[There is] a comment on the study and then you have to log in and see the comments. It's annoying because it seems as if there's a lag between when they post the comments to when I get the email… [I would receive] these reminders to respond to the comments and I'd say, 'I didn't even see that the comments were there.' So, I think there's a lag in terms of how fast I get those notifications (P-6).*

The tools were not without their faults. As previously mentioned, labeling and other instances of microcopy were not always intuitive, which may affect the ease of navigation through the tool.

Kuali Protocols. Three users had been exposed to Kuali at the time of this research; a coordinator, a submitter, and a reviewer. During the submitter's walkthrough demonstration, many pain points were observed and commented on by the user. It was the user's very first exposure to the tool.

Off the bat, the user questioned why the tool is called "Kuali Protocols" on their university student dashboard. The user said they would not have known that that the icon and name were in any way related to the IRB. The user paused at the second data field, a dropdown menu labeled "Lead Unit," (see Figure 10) saying they had no clue what that was in reference to, but a choice was required. The menu listed dozens of choices, but none of the choices seemed to apply to them.

> *Is it my department? I would be looking for something with the name of my program (P-9).*

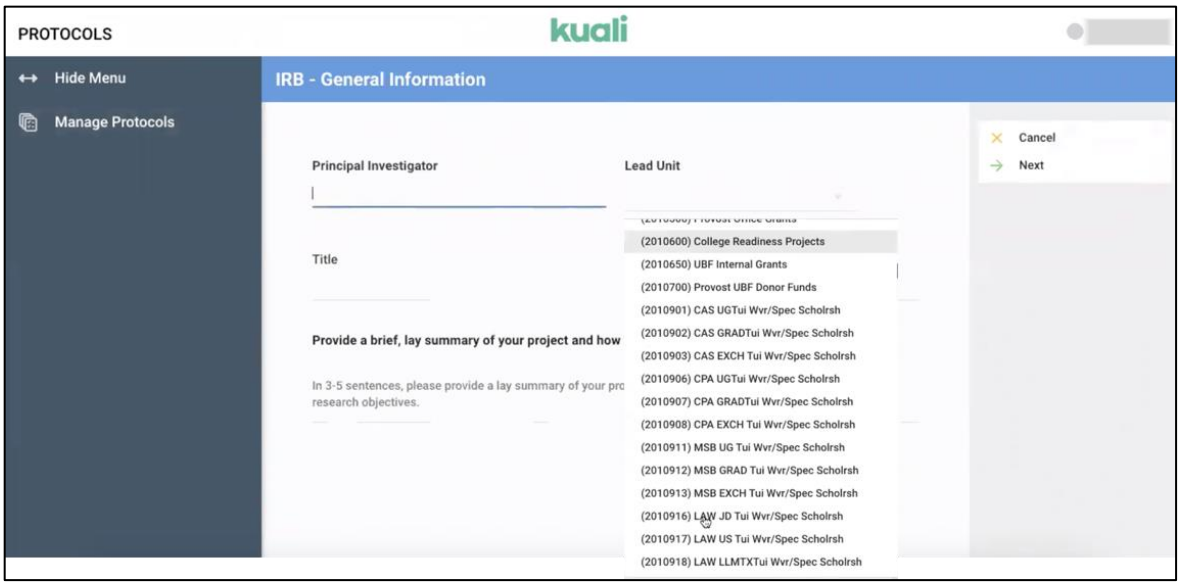

Figure 10. New Kuali submission form.

The user was required to input a start date and an end date. This was confusing to them because they weren't sure what the end date should be.

> *That doesn't make sense to me. And, if I don't have an accurate date what's going to happen? Is that going to render my study invalid?*

While going through the questions, many times the user commented that an explanation of terminology or an example of an acceptable answer would be helpful. The tool provides limited helper text and no tool tips. The user was also curious if they could start an application and come back to it during another session. They could not determine if the tool had that capability. The only option besides a Submit button and an Exit button was a button labeled "Abandon" which led them to assume they could not save an unfinished application.

A different Kuali user mentioned that in their role as a reviewer they had reviewed one submission in the tool. Their recollection of the experience was summarized as more streamlined than the offline method, however when they actually completed the review and re-routed the application back with questions in Kuali, they never got a success message or notification that the re-route had been completed.

Communication with the IRB

Application reviews are blind at their institution, according to all but one participant. In that participant's case, they knew the specific reviewer of one of their applications. The point of contact in all cases was an IRB coordinator. One participant expressed non-contact with someone on the IRB as a source of frustration during their research.

> *If you have questions about something that hasn't been covered in any of the (procedure documents)… there's a little bit of frustration figuring out who you have to talk to… it's difficult talking to an individual person at the IRB, unless you know somebody (P-5).*

Policies

Common Rule. Participants were unfamiliar with the term "Common Rule," the core principles and guidelines upon which the IRB was created. Some participants knew of recent changes to the process at their institution after the passing of the revised Common Rule in 2018 but did not know how or why there was new guidance and changes in the process.

Ethical and legal implications. Participants were not aware if there were actual legal implications associated with ethical violations resulting from research conducted under IRB approval.

Though they did not call it by name, half of participants made reference to a program called CITI Program, also known as the Collaborative Institutional Training Initiative Program, which provides a number of training modules called the Responsible Conduct of Research (RCR). The training covers core norms, principles, regulations, and rules governing the practice of research (CITI Program, n.d.). Although these participants were familiar with the training program, most participants had not completed, nor were they required to complete, CITI RCR training before being able to submit an IRB application.

> *If you hadn't done research at the institution before… you had to do some sort of compliance thing… To be honest, I'm sure I just breezed through it… You know how those things are (P-6).*

IRB board members were required to complete the training; however, they did have reservations about the CITI program.

> *I like the CITI training… I think it's a good, solid training. I will say, what might be helpful would be more oversight around that. Because my CITI training expired, and I need to do that again… It seems to be, after the first submission, a little bit of an honor system (P-4).*

Chapter 5: Discussion

The findings have demonstrated that the satisfaction with or attitude toward the IRB and its processes are not based purely on the speed at which the process takes from start to finish. Nor are they dependent upon the type of submission method utilized by the institution. Rather, it is the entire user journey that is taken into account. As many researchers described during the user interviews, submitting IRB applications is not an everyday task, therefor the pain points experienced during the infrequent journey become salient and are often what the user associates with the entire process and the board itself.

All institutions, regardless of size, must utilize a well-designed, usable, all-online process for IRB submission, review, approval, and program administration. It reduces the amount of human effort required to administer the program and acts as a repository for all documentation, saving office resources. Electronic signature methods are standard and accepted. Most importantly, as findings from the usability study and user interviews suggest, streamlining the process by moving it online allows for quicker feedback and more robust communication between all parties.

In taking a holistic view of a process that incorporates an online application, findings from the user interviews demonstrated that it is crucial that all user types are adequately prepared for any change that is expected going from offline to online. Providing a thorough introduction of the tool to any new users, as well as being transparent about the guidelines, mission, and goals of IRBs and ethical research involving human subjects are top priorities.

Implications for Design

Findings suggest that the requirements for administering the IRB program online include a robust online application and a streamlined process. Retaining records securely in the cloud and using a single sign-on (SSO) login process will ensure the app is accessible and seen as trustworthy by users. Eliminating as many barriers to entry as possible such as not requiring VPN access is preferable to users. A direct link from the user's portal makes the app visible and incorporates it into the user's existing online eco-system.

Application Design Recommendations

Several third-party vendors have created such tools and can be licensed to institutions. Any tool used for the administration of the IRB program will require rigorous validation of the user experience in the form of user interviewing and usability testing. Whether the institution utilizes third-party software or opts to design it themselves, recommendations for the design of the tool are the following:

Enable profiles and permissions for multiple user types. A tool administrator, or "super user," must be able to create permissions for different user types. Students, faculty, community members, and board members will require different levels of access.

Provide numerous resources for help. A knowledge base and FAQ for troubleshooting the tool is necessary, however the application must also provide contextual help and references such as tool tips, helper text in the form of microcopy, FAQs and/or sources related to the nuances that exist in questions on the form, and so on. This type of content should be written to be tailored toward the user type and the unique assistance they will need. Administrators should not simply provide a copy of the training manual provided by the vendor. Since it has been

demonstrated that IRB processes vary greatly across institutions, the assistance needed will be unique to that particular program.

Link to ethical research training. The institutions choice of ethical research training modules must be linked in the application. For instance, a link to CITI training modules should be accessible via the tool, with clear instructions and defined goals tailored to the institution. The app will indicate if and when the training has been completed and if a recertification is necessary. The tool should provide contextual references throughout the application process. For example, terminology that is required to be used by the guidelines but is not nomenclature or content a user may be used to using or seeing should be linked to a definition in the FAQ. Perhaps for certain questions that require an answer in the submission criteria, a direct link to the topic in the 45 CFR Part 46 code will provide context and let the user know why a certain question is being asked and how to answer it. Additionally, links to the department where the IRB is housed that contains the mission and points of contact for the IRB should be easily accessible via the tool.

Design the user interface (UI) cleanly and simply. For programs using third-party software, every possible opportunity for customization should be taken. Again, since boards and processes vary across institutions, a one-size-fits-all UI is not appropriate. Branding and styling according to the institution's guidelines need to be provided to the vendor during the setup. As much as possible, the UI should mimic other commonly accessed institution apps in design and pattern for consistency. Labels and microcopy should clearly explain the purpose of the information displayed or the interaction about to be taken. This is particularly important for easy navigation throughout the application and helping the user to complete tasks. Provide

instructional text for elements like text boxes; if an answer has a long form text field, copy should prompt the user with text indicating "Up to 200 words."

Provide templates that can be used for submission. If a program or institution's research is primarily focused on a small number of subject areas, templates tailored to those types of research will greatly improve the user experience by eliminating redundancy and reducing confusion. For example, a template for research that does not include risk to vulnerable populations could bypass questions related to that and only display relevant questions. On the backend, if the application requires answers to all questions, that information will be pre-filled. Participants whose institution utilized this functionality reported that it makes the initial process of filling out forms simpler and quicker. Another way to handle easing the experience of filling out the form would be to use if/then functionality throughout the form. Depending on an answer a user may be taken down one path or another, again bypassing non-relevant questions.

Provide functionality to track changes made in a submission. This can take the form of inline visual indicators where an edit has been made, making the form easily scannable by the reviewer. Similarly, in the case of more information being required or a specific question about an entry, inline commenting will help the researcher to determine exactly where and what the question is. A navigational aid in the form of a sidebar that includes anchor links to the locations of changes and/or comments would serve as a type of "to-do" list for the user. In addition to convenient inline commenting, a location in the app should house functionality to provide more detailed and longform communication capability between users. When action of any kind is taken on a submission, notify the researcher via the app's inbox and via email. Similarly, notify reviewers via inbox and email when some action is required. Periodic reminders will be sent via

both methods when something is pending an action. Mentioned frequently by interviewees as a pain point in the process, this type of communication is crucial to get right.

Indication of status. When a user logs into the tool there should be a display for the status of a submission. Whether the user is a submitter or reviewer, the display will include who has interacted with or viewed the submission, who is currently in possession of the submission (who is currently required to take action), and what happens next. The guidelines for the time the submission may stay in the current status should be displayed as well. All activity will be time and date stamped. A status indicator that visually represents the process or where the user's submission is in the review process is crucial. Users are familiar with this type of feature in many different contexts and are immediately recognizable. For any other visualization or aid used in the application, it must be easy to determine its purpose interpret its content.

Make available an archive of past activity and past documentation. An easily accessible archive of past approved submissions allows users to reference past projects to get answers to questions they may have about a current submission. Additionally, any documentation or attachments that were attached to a past submission can be used again on new submissions. If a user is replicating a past study, or a study very similar to a past one, being able to duplicate a past submission and make relevant edits to it is convenient for the user.

Utilize e-signature functionality to serve as official acceptance and entrance into the record. By nature of the user being logged in with a unique identifier and authenticated by the system, clicking the theoretical "submit" button should serve as their signature. The researcher's e-signature is required at the end of a submission; the reviewer's signature once a submission is approved; and an administrator, the department chair for example, is the final signatory. All of these interactions are time and date stamped. Processes among institutions vary in the

requirement of a physical signed approval letter or document. The approach of not requiring anything physical should prevail whenever possible.

Process Design Recommendations

To successfully implement an all-online process of IRB submission and approval, it is necessary to rethink the current process at an institution. While the tool may be flawless and easily accessible to all user types, the success of the implementation and adoption is reliant on several factors that are detailed in this section. The recommendations for designing or re-designing the process are the following:

Include stakeholders in the process of instituting the online program. A user-centered design approach should be taken at the beginning stages of program implementation. This includes bringing together cross-disciplinary stakeholders to provide input about their unique needs and possibly assist in evaluating third-party tools and have input on the features and functionality to make sure their needs are met. As noted in the research, staff that currently perform manual functions will most likely be performing other job duties outside of the administration of the IRB process and can focus more time on those. Depending on the size of the institution and the need, it is possible that staff resources may be reallocated elsewhere in the institution.

Enable all user types to complete all duties inside the application. All users must be able to substitute any manual process they currently perform with the capabilities of the tool. This will enable the eliminate of all physical paperwork associated with administration of the program. The application must be linked from the university's online portal and from the sponsored research or institutional research website.

Study existing IRB guidelines and determine opportunities for change. Board members and administration must take a deep look into the existing, possibly archaic and outdated, deadlines, requirements, and policies of the program. The group needs to factor in how the new online process will streamline their duties and re-establish guidelines for review time accordingly. It is possible the timelines cannot or do not need to change for different reasons but taking the time to evaluate and verify that no changes are necessary should be required. This is also an opportunity to evaluate the makeup of the board membership and modify it as necessary.

Develop a mission statement for the IRB. The board needs to have a clearly defined set of guiding principles that are visible to the rest of the institutional community to convey legitimacy and build trust in the process and into the board itself.

Require ethical research training for all user types. Any partaker of the IRB process at an institution must understand the basis for which the IRB was incepted and the ethical implications that, in the absence of the IRB, could be destructive to individuals and communities as noted in previous research on the topic. Since the CITI modules on ethical research is a commonly accepted and utilized form of this education, institutions should make its completion required before any submission can be or reviewed. Ethical research education should be paired with other topics such as information literacy in entry-level courses and seminars. After a period of time, perhaps two years, all users must demonstrate they still have an understanding of the IRB and research ethics, through a minimal refresher training course completed on their own time.

Require application user training for all user types. Since the success of the process hinges heavily on usage of the online application, all users of the tool must undergo formal training on how and why to use it. This can be coupled with the CITI training. Students and new

researchers could complete these requirements at the beginning of the semester when they are enrolled in a course that will require research with humans. Reviewers and administrators will be required to undergo thorough, tailored training of the tool before it goes live, and should be appropriately retrained in some capacity if a new process or feature is introduced, or if their role changes. Tailored, in this case, means the content must be relevant to the type of research they will be evaluating.

Notify all user types of application updates and process changes. Timely updates must be communicated to the user base any time an update to the application or process has been made. These communications are made via email as well in any sort of announcements module on the university portal.

Maintain transparency into the program's mission and purpose. The institutional community should not be afraid of the IRB. They shouldn't look at the process as daunting or negative, rather, they should see it as a necessary and beneficial part of having the privilege of doing research. Through transparency and openness with the community, hopefully the process and the board itself are seen as an important voice and leader when it comes to making the institution a beacon of rigorous research and knowledge.

Chapter 6: Conclusion

This research examined the factors that elicit a positive or negative perception of the IRB and its processes by researchers and members, and the findings were evaluated in order to suggest a framework for structuring the IRB process at an institution.

Many factors negatively color a researcher's view of the IRB they have to work with at their institution. If the process is not transparent and the submission method not easily learned and accessible, the researcher questions the validity of the IRB and the reason for its existence. Institutions and IRBs need to make educating their community about ethical research practices a priority, which includes showing that without guidelines the history of questionable human research practices is bound to repeat itself. Researchers want to take pride in their output and can only benefit from a positive, or even unremarkable, experience with the IRB that allows the research to happen.

Limitations

There are a few limitations to this research. The collection of data spanned the course of several semesters, in the middle of which the Common Rule revisions were introduced and adopted. Additionally, the research started under the premise of continuing the digital signature project in which a task was to design a solution for replacing wet signatures on paper IRB applications at the researcher's home institution. In the span of those several semesters, the institution hired a third-party vendor to administer an online submission tool. The research evolved and took shape to encompass the process design as well as design implications for an online submission tool. Because of these factors, the results and discussion are based on what was found or observed at the particular moment in time when the data was collected.

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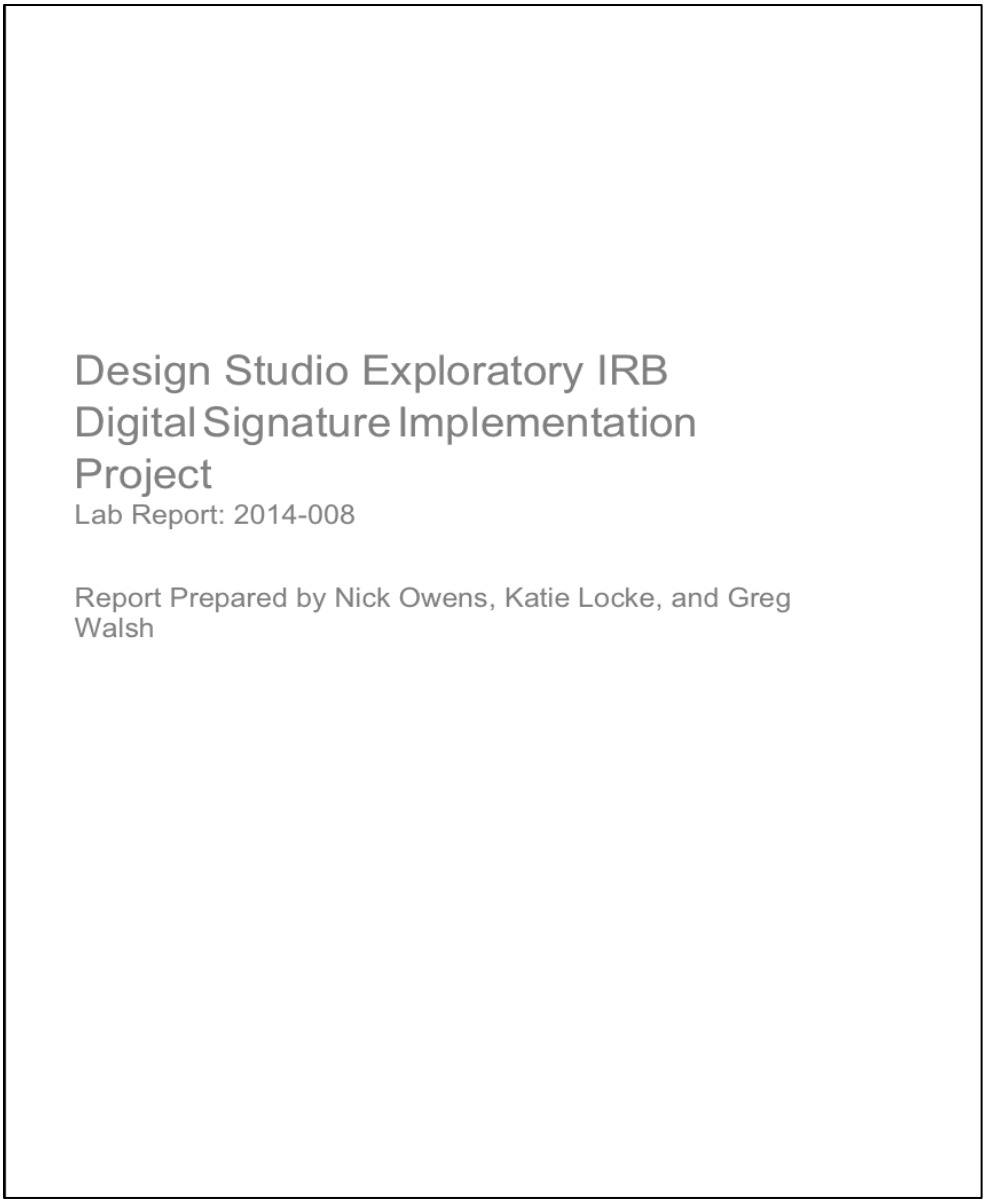
Appendix

Design Studio Lab Report

Link to report: https://mdsoar.org/handle/11603/13020


Design Studio Exploratory IRB Digital Signature Implementation Project
Lab Report: 2014-008

Report Prepared by Nick Owens, Katie Locke, and Greg Walsh

Participant Consent Form

Whom to Contact about this study:
Principal Investigator: Katie Locke
Department: Division of Science, Information Arts, and Technologies
Telephone number: 410-977-0787

CONSENT FORM FOR PARTICIPATION IN RESEARCH ACTIVITIES

Investigating process improvements for Institutional Review Board application lifecycle

I. INTRODUCTION/PURPOSE:
I am being asked to participate in a research study. The purpose of this study is to identify process improvements to the existing Institutional Review Board application lifecycle in various sectors. I am being asked to volunteer because I have already, or may in the future, completed the IRB approval process for research involving human subjects. My involvement in this study will begin when I agree to participate and will continue intermittently for six months.

II. PROCEDURES:
As a participant in this study, I will be asked to provide feedback and articulate my decision-making processes on various elements of a process. I will be asked to answer questions about a process related to research I have already done with human subjects, or that I may do in the future, AND/OR I will be observed completing an online IRB application form process. I understand that I am not being tested and I am only helping the researchers identify flaws in the existing process(es). My participation in this study may occur one or more times over the course of six months.

III. RISKS AND BENEFITS:
My participation in this study does not involve any significant risks and I have been informed that my participation in this research will not benefit me personally, but may help lead to development of new processes and technologies.

IV. CONFIDENTIALITY:
Any information learned and collected from this study in which I might be identified will remain confidential and will be disclosed ONLY if I give permission. All information collected in this study will be stored in a secure location. Only the investigator and members of the research team will have access to these records. If information learned from this study is published, I will not be identified by name. By signing this form, however, I allow the research study investigator to make my records available to the University of Baltimore Institutional Review Board (IRB) and regulatory agencies as required to do so by law.

Consenting to participate in this research also indicates my agreement that all information collected from me individually may be used by current and future researchers in such a fashion that my personal identity will be protected (through image or voice manipulation). Such use will include sharing anonymous information with other researchers for checking the accuracy of study findings and for future approved research that has the potential for improving human knowledge.

Images and video are recorded during the research study:

☐Yes, I give permission to use my image/video in scientific publications or presentations.

☐No, I do not give permission to use my image/video in scientific publications or presentations.

V. COMPENSATION/COSTS:
My participation in this study will involve no cost to me.

VI. CONTACTS AND QUESTIONS:
The principal investigator, Katie Locke, has offered to and has answered any and all questions regarding my participation in this research study. If I have any further questions, I can contact Katie Locke at 410-977-0787 or Kathryn.locke@ubalt.edu. For questions about rights as a participant in this research study, I can contact the UB IRB Coordinator at 410-837-6199, irb@ubalt.edu.

VII. VOLUNTARY PARTICIPATION
I have been informed that my participation in this research study is voluntary and that I am free to withdraw or discontinue participation at any time.

I will be given a copy of this consent form to keep. If I sign this form electronically, I will be emailed a confirmation.

VIII. SIGNATURE FOR CONSENT
The above-named investigator has answered my questions and I agree to be a research participant in this study. By signing this consent form, I am acknowledging that I am at least 18 years of age.

Participant's Name: _____ Date: _____
Participant's Signature: _____ Date: _____
Participant's Email Address:
Investigator's Signature: _____ Date: _____

Participant Intake Survey

Whom to Contact about this study:
Principal Investigator: Katie Locke
Department: Division of Science, Information Arts, and Technologies
Telephone number: 410-977-0787

INTAKE SURVEY FOR PARTICIPATION IN RESEARCH ACTIVITIES

Investigating process improvements for Institutional Review Board application lifecycle

1. Email address
2. What is your current position at your institution?
3. What institution do you currently attend, work for, or represent for the purpose of this research?
4. Does your institution or the institution you are representing currently use an electronic filing and approval system for IRB protocol submissions? Yes, No, I'm not sure
5. Do you currently sit on an IRB at your institution or another institution? Yes, No
6. What is your experience with SUBMITTING IRB protocols for research with human subjects? When was the last time you did it? Was it via paper forms or electronic? What type of research were you conducting? How long did it take to be approved? Did you have to make modifications? If you do not have experience submitting, please answer "N/A."
7. What is your experience with REVIEWING IRB protocols for research with human subjects? When was the last time you did it? Was it via paper forms or electronic? How long does an application typically take for approval? If you do not have experience as a reviewer, please answer "N/A."
8. Do you currently teach or advise students or other mentees who submit protocols for IRB approval? Yes, No

9. If you currently teach or advise students or other mentees who submit protocols for IRB approval, do you have any that will be submitting in the near future? What type of research are they conducting? If not, please answer "N/A."
10. Do you currently have a pending application submitted for IRB approval? Yes, No
11. Will you be submitting a protocol or application at an institution for IRB approval in the near future? Yes, No
12. When will you be submitting? Date can be approximate. Month, day, year
13. When are you are available to discuss your IRB experience in more detail using Zoom or a similar video chat application? Date and time ranges can be approximate i.e. "Monday evenings in January are best for me."
14. If applicable, I may ask you to give me a live demo of either your paper IRB application process or your electronic filing process while sharing your screen. Are you open to doing this via Zoom or a similar screen sharing application?

IRB Approval Letter

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October 3, 2018

Kathryn Locke
University of Baltimore
1420 N. Charles Street
Baltimore, MD 21201

RE: **IRB Protocol UB19-13 – Approved under Exempt Review**

Dear Kathryn,

This letter serves as official confirmation of the Institutional Review Board's review of your protocol for a study entitled "Ethical research approval in a timely manner: IRB process flows and implications for redesigning them", submitted for review on September 12, 2018.

The Institutional Review Board considered your request and concluded that your protocol poses no more than minimal risk to participants. In addition, research involving the use of widely acceptable survey/interview procedures where the results are kept confidential and the questions pose minimal discomfort to participants is exempt from IRB full-committee review per 45 CFR 46.101 (b) (2). As a result, the Institutional Review Board has designated your proposal as exempt.

Investigators are responsible for reporting in writing to the IRB any changes to the human subject research protocol, measures, or in the informed consent documents. This includes changes to the research design or procedures that could introduce new or increased risks to human subjects and thereby change the nature of the research. In addition, you must report any adverse events or unanticipated problems to the IRB for review.

If you have any questions, please do not hesitate to contact me directly by phone or via email.

As authorized by Dr. Ann Cotten
Chair, Institutional Review Board

Stefanie Dwyer
Coordinator, Institutional Review Board

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