

Design Studio Exploratory IRB Digital Signature Implementation Project

Lab Report: 2014-008

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1. INTRODUCTION

With a specific project in mind, we explored the implementation of an electronic Institutional Review Board (IRB) application for research involving human subjects, that would also require a user to provide a “digital signature” in compliance with current regulations that would meet the needs of the current IRB staff at the University of Baltimore. An initial discussion was had with the IRB Coordinator about the general expectations and some important details that would help guide our creative process. The following paper will provide some background to the topic along with specific information regarding our process as well as final outcomes and suggestions about an IRB electronic application and digital signing integration. It will also document the creation and feedback gathered around our paper and technical prototypes as well as our recommendations for future implementation and further design.

2. BACKGROUND

The main purpose of the project was to understand how the IRB application process works and determine how best to implement a digital signature to eliminate a paper intensive process. To help understand how this is possible, the United States put into effect the electronic signatures in Global and National Commerce (ESIGN) Act on October 1, 2000 (ESIGN Act, 2000). This laid the groundwork for the allowance of digital signatures, which as stated “allows the use of electronic records to satisfy any statute, regulation, or rule of law requiring that such information be provided in writing, if the consumer has affirmatively consented to such use and has not withdrawn such consent” (ESIGN Act, 2002).

With any government statute comes stipulations and this is no exception. Under the revisions to the E-SIGN Act of 2000, it makes clear that a digital fingerprint must also be created in which both the signatory can review and the accepting party can reproduce. This should include the signer's name or similar identifier (for instance a university identification number), the date and time it was signed, and must be attached to what was agreed upon. It is therefore the responsibility of the accepting party to devise a way in which they are able to produce the above-required documentation on the signatory's digital fingerprint in order to suffice for legal purposes under the E-SIGN Act. We will next discuss specifically some of the institutions that have implemented this process and the ways in which they have been able to accomplish it.

3. WHO IS USING DIGITAL SIGNATURES?

We did some background research into discovering how other institutions had incorporated technology into their IRB application process. We found a number of them did, in fact, accept digital signatures. It can be broken down into two specific areas of technology used in the IRB application: simple Adobe digital signature creation, and online portal digital signature (with some form of authentication for access). A majority falls into the first category, which is described as simply creating a digital signature in Adobe Reader or Acrobat and placing it on the completed IRB application in PDF format. It should also be noted that this area of digital signatures, users had a varied approach to submittal as some still allowed for paper submissions while other required digital application submission with a digital signature.

As for the other technology in use for digital signature collection, most was via some form of online portal requiring applicants to authenticate (generally through a university-supported single sign on (SSO) approach) in order to gain access and complete an IRB application. These online portals allowed not only for a completely digital process requiring no physical paper form, but also a system by which a digital signature could be gathered and processed. This appeared to be incorporated mostly at larger institutions, which could be due to a number of factors that may include increased resources and number of applicants utilizing the IRB application process each given year. While the use of fillable PDF forms with digital signature functionality was more prevalent than the online portals viewed, it appears the number of online portals being utilized by institutions is growing rapidly due to ease of use, useful and robust administrative functions, specific application progress tracking options, and accessibility of services. Several examples have been listed in the reference section of this paper, which provide excellent supporting documentation to both forms of digital signature utilization.

4. HEURISTICS

It is always important to consider some best-practice heuristics when designing an online interface. While there is little heuristics related specifically to collection of digital signatures, we did find some guidelines to help inform the creation and implementation of the online IRB application and collection of electronic signature. When developing the digital application, it was important to consider several heuristics that included user control

and freedom, implementation of common language (where possible), and a mobile-friendly design.

While designing the prototypes, we wanted to ensure we included words, phrases, and concepts that were familiar to the user and present information in a simple, natural, and logical order. This proved to be a challenge given the sensitivity of the information and potential legal implications to deviating from what had already been created. When we were gathering feedback from end users, we asked for opinions about the common language and terms they might use when explaining the various questions on the application. This affords the best experience for the end user by not using technical terms and jargon, which may only be comprehensible to IRB staff.

Also, when creating a web portal that is made for both advanced (repeat) as well as novice (first time or newer) users, it is important that the user interface (UI) is flexible which allows both types of users to be comfortable with the content and increase ease of use. To accomplish this, we tried to make it very easy to “undo” and “redo” actions. In addition, we created both a “self-guided” and “assisted” versions of the IRB application, which would allow advanced users to move quickly through the process with less information while novice users can receive helpful and descriptive information to assist in determining correct questions responses.

Last, we wanted to make sure the web portal could be utilized on a mobile device. While we did not create a mobile version in our prototype, we did incorporate some mobile best practices in our design that would allow for easy conversion of information when a solution had been determined. This included ensuring all irrelevant, unnecessary, and

distracting information and content was removed. This allows a mobile user to not be overwhelmed when viewing any information on a smaller screen. In addition, we made sure that icons and buttons were easily recognizable symbols or well labeled. It should also be noted that there is a low expectation that people will be completing the IRB application on a mobile device, but there is a high expectation that they will log into the portal and verify their status via a mobile device such as a tablet. This should be considered when it comes time to determine a final product.

5. INTITIAL CONCEPTION

The project started with the creation of a process flowchart. This helped us determine all of the steps in which an end user would go through in the current paper process of an IRB application at the University of Baltimore. Once visualized, we then began brainstorming as to how the process could best be achieved through an electronic tool that would easily capture the digital signature. After several considerations, we felt the best application that would create a superior user experience would be through a web portal. This would allow for the end user to easily access the creation of a new IRB application, check on the existing status of an application, approve a collaborator/ additional researcher status, allow for messaging between all involved parties, create a workflow between all required parties, and give easy access to digital signatures created including verification by all parties. Given the current structure at UB, we felt it would be best implemented through the current MyUB portal via an IRB icon (see appendix).

6. PAPER PROTOTYPE

6.1 Design

The paper prototype was drawn by hand to give the appearance of what it may look like when completed. The process of having users test the paper product allows their experience and opinions to be untainted, thereby eliminating any bias towards certain ways an application should look and/or function. This testing process allowed for quick corrections to be made when needed and adequate feedback given its “rough” look. The prototype was designed in such a way that when testing it with a user, the “screen” scrolled when necessary, “buttons” could be selected, and “text” could be input into text fields. When certain sections required a popup action, a paper version of the popup was presented. The look and feel of the paper prototype, along with the feedback collected, guided the eventual design of the technical prototype. See Appendix A for samples of the paper prototype.

6.2 Testing and Feedback

The paper prototype was shared with several people who have varied levels of experience with the IRB application process as it is implemented at this point. This phase of testing included users who have completed several IRB applications as well as those who are just starting to think about using the application for upcoming research. Students and faculty both tested the prototype. After they reviewed the prototype and attempted to utilize them for completion of several tasks, we gathered some feedback about how their experience was and what they may like to have improved.

6.3 Evolution and Lessons Learned

While we had initially planned to leave the paper prototype unchanged throughout the feedback process, we decided after our initial feedback that it would be best to create multiple iterations. This would allow for further understanding of challenges met by the users and move toward a stronger technical prototype when the time came. One user was very excited about the prospect of an electronic IRB application and digital signature as well as the potential for a web portal in which they could check their IRB application status. They have filled out several IRB applications and felt it would be an asset to them.

"I think this is wonderful. It is extremely useful and will be much easier to complete in this new format."

-User 2

All users who provided feedback had trouble with the wording of several questions...

"There should be something that elaborates on what the rules are for something to be considered 'deception'"

-User 3

"The question of whether the research needs to be approved by agency heads is a double-barrel question."

-User 1

"Some of these questions seem to be asked in different ways a few times on the application. They are redundant."

-User 2

The use of attachments was also difficult and somewhat confusing...

"There should be some sort of confirmation that the file I selected actually attached."

-User 2

The first user was hoping to get information about how soon their application may be processed based on the information provided. This information was not originally included in our design, but language was implemented immediately following to let users know an estimated time for application processing.

"I would really like to know how long it is going to take for my application to be processed. That is very important to me."

-User 1

"Will there be a confirmation to let me know that my application can be expedited?"

-User 2

After the all the feedback had been gathered, we reviewed the paper prototype and discussed how each user had used the application process. Given the uniqueness of each user's interaction with the application process, we determined the best ways in which each of the above suggestions could be incorporated in the technical prototype.

7. TECHNICAL PROTOTYPE

7.1 Design

We began developing the technical prototype immediately following the synthesis of information gathered through feedback on the paper prototype. After refining our intended project outcomes, we decided Axure, an interactive technical prototyping tool, to be the best tool for technical prototype implementation given its features and ability for rapid prototyping. Given the nature of the paper prototype, we immediately pared down several of the screens to be combined into a single screen to eliminate excessive scrolling and unnecessary repeat actions (i.e. selecting "yes" or "no" to each question and then clicking

“next”). We also determined that it might be best to combine similar questions to increase efficiency and flow. A prime example of this was moving all questions that had attachment options (consent form, research protocol) to a single page. This allowed for the repeat action to be completed all at once and give a logical flow to information gathering outside of the application.

7.2 Feedback

The technical prototype was once again shared with several people who have varied levels of experience with the IRB application process as it is implemented at this point. It is important to note that while one person also provided feedback on the paper prototype, the rest had not seen the paper prototype before reviewing the technical prototype. The presentation of information was completed in several different methods that included presenting the prototype in person via a laptop computer and presenting the prototype through a screen sharing software (join.me) with audio discussion via cellphone. While they involve very different methods of information sharing, we do not believe this affected the quality of their feedback.

7.3 Evolution and Lessons Learned

Similar to the paper prototype, the technical prototype saw small evolutions between each given set of feedback by users. This allowed for several iterations culminating to the final iteration included in the appendices of this paper. The initial reactions we received in the feedback were that users liked our prototypes and felt they were great improvements on the current process due to their accessibility and ease of use. The

implementation of both a web portal for easy application and digital signature access were well received and most users saw this as an extension of an existing technology (MyUB portal), which already felt familiar.

Through the technical prototyping we found that a lot of users had the same problems regarding the wording of questions. Being unsure of how we could change this information, we decided to leave most of it unchanged.

“What does this question even mean? I have no idea how to answer it as it feels like they are asking me something else.”
-- User 4

“I do not like the use of that language. “Behavior” is a very subjective term. It is very misleading.”
-User 3

The users really liked the design of the administration portal. They felt it was a great tool to access information about existing IRB applications as well as new ones.

“This makes status checking so simple. When is this going to be implemented?”
-- User 5

“I access IRB stuff on occasion and can tell you this will be a huge benefit to anyone who uses it.”
-- User 6

We were initially concerned about the amount of scrolling that a user would have to do over the course of the application. The feedback we received did not however see this as a concern and preferred it be kept together.

“I thought it was a good amount of scrolling. I’d prefer the questions that are similar stay together.”
-- User 2

There was a little confusion by one user regarding the “attach” feature in which they were unsure whether it was required or if plain text was required.

“I am not sure whether I need to put in plain text, attach an item, or do both. Clarification at the top would be helpful.”
-User 3

It appeared that the issues that were changed between the paper and technical prototypes were well received. As for some of the items that were not changed (wording of some questions), they continued to be a challenge for the users. It should be reviewed with the IRB Coordinator and discussed whether changes can and should be made.

8. CONCLUSION AND RECOMMENDATIONS

Overall, the implementation of an electronic IRB application along with digital signature appeared to be highly received by end users. Ultimately, the current paper driven process continues to challenge both the users and IRB processing staff given its process requirements, physical limitations, and the lack of flexibility afforded in an electronic process. Furthermore, the amount of technological tools and resources that exist are currently being implemented across the country and would greatly benefit the IRB staff and users through their process efficiencies while also increasing sustainability (a pillar of the university philosophy).

We offer the following recommendations:

1. [Create an online IRB application that can be accessed easily via the MyUB portal.](#)

2. Design an administration screen(s) so that the actions are easily completed, i.e. creating a new application, viewing completed applications, and checking the status of pending applications.
3. Develop an administration screen for the IRB coordinator that is different than for the IRB applicant with all features necessary to approve, reject, or follow-up on submitted applications.
4. Review all questions to see if any can be shortened or worded differently, according to federal IRB standards.
5. Eliminate questions in the application that are repeated. Instead, apply logic to the questions the first time they are asked. This will be most beneficial for determining whether an application is considered exempt and/or expedited. For example, if question A is answered "yes", then condition B is met.
6. Allow a student or faculty member's UB ID number to serve as their legally binding digital signature in the process.

9. REFERENCES

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10. APPENDICES

10.1 Appendix A: Paperprototype

Attached

10.2 Appendix B: Technical prototype

The URL to view the technical prototype built with Axure is available at http://bi5576.axshare.com/myub_home.html