A Web-Based System Facilitating Pace University’s IRB Application Process

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Abstract
Institutional Review Boards (IRBs) were established as part of the National Research Act of 1974. They are governed by the Code of Federal Regulations. Their purpose is to protect the rights and welfare of research subjects who participate in biomedical and behavioral studies [1]. The Food and Drug Administration and Department of Health and Human Services oversee these IRBs and have set requirements they must adhere to. How these requirements are met is up to the individual IRB. Whether manual or automated, the process can be categorized as a document flow system. This paper discusses the work involved to convert Pace University’s IRB application process from manual to an automated system.

1. Introduction

Taken from the Wikipedia definition, an institutional review board (IRB) is a committee that has been formally designated to approve, monitor, and review biomedical and behavioral research involving humans with the aim to protect the rights and welfare of the research subjects. In the United States, the Food and Drug Administration (FDA) and Department of Health and Human Services (specifically Office for Human Research Protections) regulations have empowered IRBs to approve, require modifications in planned research prior to approval, or disapprove research. An IRB performs critical oversight functions for research conducted on human subjects that are scientific, ethical, and regulatory [1]. IRBs were developed in response to research abuses early in the twentieth century and are defined in the National Research Act of 1974.

According to the FDA requirements, the IRB must have at least five members. These members must not all be of the same profession and they must include at least one person who is not affiliated with the institution. And the members must have enough experience, expertise, and diversity to make an informed decision on whether the research is ethical, informed consent is sufficient, and appropriate safeguards have been put in place [1].

The IRBs are also required to obtain various documents during the research period. These documents include: trial protocol, written informed consent forms, subject recruitment procedures, information being provided to subjects, safety information. There are other documents that may be required by the individual IRB. The IRB review, whether favorable or of negative opinion, must be documented as well. Throughout the life of the research, at predetermined intervals, the IRB should review the study and assure that it is following the appropriate guidelines. Any comments made by the IRB at these times must be documented.

There are many other specifications and requirements of an IRB as mandated by the FDA and/or Department of Health and Human Services. For the purpose of our study, the aforementioned items indicate the importance of a proper document flow and archive for an IRB.

2. Current Process

Like many universities, Pace University has an Institutional Review Board (IRB) which consists of 12 members, two of whom are co-chairpersons. These members represent the schools/college of Pace University, administration, staff, and the external community. The co-chairpersons are Dr. Lin Drury and Brian Evans and Beatrice Moy is the IRB Coordinator. The current application submission process, approval process, and research oversight is a time consuming, paper centric
process which lacks proper document flow and tracking. This section will discuss in detail the current process.

The home page for Pace University’s IRB is www.pace.edu/page.cfm?doc_id=9880. From this site, a user can select the following links:

- Frequently Asked Questions
- IRB Policy and Procedures
- IRB Application Guidelines
- IRB General Checklist and Application Packet
- Study Revision Form
- Study Renewal-Termination
- IRB Confidentiality Statement

Each link brings the user to either written pages or documents to download. The IRB General Checklist and Application Packet page contains only a word document to download which is needed for the application process. This document contains the following information which needs to be submitted to the IRB:

- 15 question checklist (yes/no)
- Five page proposal form consisting of check marks, open questions, and signature
- 18 elements that are required on participant consent forms

The applicant must submit three copies of the proposal via mail or in person to Pace University’s downtown New York campus.

Requirements and next steps vary depending on the nature of the research. There are three types of review:

- Exempt – research where there is no risk to subjects. This only requires one co-chairperson approval.
- Expedited – research where the risk to subjects is minimal. This requires both co-chairpersons to approve.
- Full board – research where there is some risk to subjects or subjects are considered to be members of a vulnerable population. Requires approval of all IRB committee members.

Exempt and expedited have similar processes. A hard copy is sent to both co-chairpersons. In the case of exempt, the IRB Coordinator will assign a co-chairperson to review the application. The review process usually takes 2-3 weeks. If there are any issues with the application and revisions are needed, the approver will contact the applicant either via email or mail. The applicant will then have to submit a revision form and mail or deliver in person. Approved research is good for one year. At that time, if the study is not complete, the applicant must submit a Study Renewal form.

The approval process for applications requiring full board review can take up to two months. One reason for this is the board does not usually meet more than once a month. The revision process is similar to exempt and expedited but the full board needs to approve.

On average, Pace IRB receives about 7 proposals each month. However, this past February, 26 proposals were submitted due to new courses offered at Pace. For the months of January and February combined, there were 31 exempt proposals, 10 expedited and 2 that required full board review.

Of those submitted, about 2% are rejected due to incomplete or inaccurate forms. In one particular case, the full committee reviewed a proposal in the first week of February and a response with feedback was emailed to the applicant. The applicant resubmitted the proposal via email. This exchange of responding and resubmitting occurred over a 2 month time before the proposal was finally approved. One reason for the delay was having to review the entire proposal once resubmitted rather than the fields (data) actually being modified as there was no indication what was changed. Another reason for the delay was the applicant, at one point, resubmitted the incorrect version of the proposal.

In summary, the current process is very manual, time consuming, and prone to mistakes or lost paper work. It is difficult to track applications and research in progress. The guideline for submission is confusing resulting in proposals not complete or not submitted in a timely fashion.

3. IRBs at Other Universities
Any institution involved in biomedical and behavioral research involving humans must comply with the FDA regulations as stated in the introduction. However, the FDA guidelines do not stipulate how these institutions must abide by the requirements. From researching various universities, three implementations of an IRB application process have been found:

- Manual
- University supported web-based application
- Vendor supported web-based application

The majority of the universities researched have a manual system for processing applications. The University of Oklahoma, University of Minnesota, University of Alaska, and Washington State University, to name a few, have manual systems almost identical to Pace University.

Many universities do have their own supported web-based application. These universities include: Duke University, Park University, University of South Florida, and Oregon Health and Science University. In every application, there is a secure login.

Two companies were found which offer outsourced solutions for a university. IRB Services offers a web-based solution for research ethics and IRB application processing. They process over 20,000 applications per year with over 40,000 registered users and 200 IRB committees. IRB Services provides this service in the UK, Australia, Germany, and most recently Canada and the United States [3]. The second company is IRBNet which was established in 2001[4]. Similar to IRB Services, IRBNet fully supports IRB application processing requirements. IRBNet runs on any platform and can support any size institution. IRBNet offers maintenance, support and training.

4. Objectives of New System

The requirements for the proposed automation of the application process have been clearly defined. The customer wants a web-based system to eliminate the dependencies on hard copies and the mail service. The requested mode of communication is via email.

The new system will enable an applicant to submit their proposal, upload consent forms and other required documentation, and receive notification of receipt of the application. The IRB Coordinator would then receive an email notifying him/her that a new application was submitted. In the case of an exempt proposal which only requires one co-chairperson approval, the new system will automatically assign a co-chairperson to the proposal using a function to determine which co-chairperson has the least amount of active proposals. An email will be sent to the person assigned. In the case of a proposal requiring full board review, emails will be sent to all committee members.

Once submitted, applicants will be able to log into the system over the Internet to view the status of the application. They will also be able to take other actions such as modify applications and resubmit, request extension to research, etc.

The approvers will be able to log into the system and view all applications. If they have been assigned to an application, they can make comments on each data element of the application and automatically email the applicant with those comments. They can also approve the application which will then send an email with a specific letter stating that approval.

Both the applicant and approvers will be required to register in the system and create their login credentials for security purposes. Each type of user will have specific rights associated with their access. For example, an approver can see all applications submitted but an applicant can only see those they are associated with.

5. Methodology Used for System

Below is a list of the software used in creating this application:

- Active Server Pages (ASP) utilizing client and server side VB Script
- Data shaping – a feature of ADO object that allows creation of hierarchical recordsets giving tremendous power over manipulating and displaying data
- Java Script and HTML
- SQL – SQL statements, views and stored procedures
- style sheets
- Free ASP Upload - a free script that allows for uploading files/forms [5]

Appendix A is a screen shot of the logon page, after the user clicks “Forgot my password” and enters an unknown email address. Appendix B shows the page where the user uploads the required Certificate of Completion for the NIH tutorial. Appendix C shows the final submission page. They all exemplify the methodology used in the development of the application.

The application flow, database design, and functions will be discussed in this section.

5.1. Applicant Program Flow

The application flow from the user view point is shown in Figure 1. The IRB system will have 2 types of users: Applicant and IRB Committee member. The applicant user will include the Principal Investigator and other researchers listed in the proposal. The Committee member user will include the co-chairpersons, the Committee Board members, as well as the Coordinator.

These will initially include active proposals and those waiting for approval. For unapproved proposals, the user selects the proposal to see the full detail. From here, the user can approve the proposal or make comments as to why the proposal was rejected. In both cases, an email is sent to the researcher(s).

Once an applicant user signs in, they will see a page listing all proposals they submitted or saved. For rejected proposals, they can update the necessary information and resubmit. For saved proposals, they can continue working with the proposal and submit for approval when complete.

The applicant user can also select to create a new proposal. This will bring him/her to a new screen to enter the required information. The user can hit ‘save’ at any time and come back to the proposal at a later date. The questions asked will differ depending on the type of proposal the user is creating. When the user is finished with the proposal, they will hit ‘Final Proposal Submission’, see Appendix C, and an email will be sent to them and to the IRB committee as described in the previous section.

5.2. Database Design

The database design began by gathering the business requirements and converting them into a logical data model. The deliverable of the logical modeling was the Entity Relationship (ER) diagram located in Appendix D. The physical database was created by transforming the logical data model’s entities into tables, attributes into columns, business units into data types and constraints, and implementing logical relationships by assigning referential constraints. The IRB system table names and description can be found in Figure 2.

| Person | stores the name info, address info, contact info of all people that have pertinence/belong to the system such as Applicant (person who submits the proposal); proposal Principal Investigator(s), Co-Investigator(s), faculty advisor(s); and IRB committee members |
| ProposalType | stores the types of proposal and their short description |
| Proposal | stores the submitted proposal’s info by the applicant |
| Role | stores the roles that a person can play as part of the |
5.3. Procedures and Functions

This section will discuss data validation and functions created. All required fields on a page are denoted by an asterisk, "*". For data validation, VB Script functions were used:

- `isEmail()` – checks if the provided email is a valid email.
- `isNumber()` – checks if the entered value is numeric, e.g., zip code.
- `isGoodString()` – checks if the entered value is a good string.

JavaScript object’s events such as `onclick()`, `onsubmit()`, and `onchange()` where also used during validation. When uploading files, the uploaded file is validated to be a word document by checking for the extension of .doc or .docx. Validation also occurs during user profile setup or updating. The email provided is checked against emails known to the system in the `sp_PersonInsertUpdate` SQL stored procedure.

One of the features of the new application is the ability to email applicants known to the system. Below shows code to email a user notification that their password has been established. The first section is code to send an email. The second calls this code to send a forgotten password.

```vbnet
<% Set objCDOSYSMail = Server.CreateObject("CDO.Message") Set objCDOSYSCon = Server.CreateObject("CDO.Configuration") With objCDOSYSCon .Fields("http://schemas.microsoft.com/cdo/configuration/smtpserver") = "email.pace.edu" .Fields("http://schemas.microsoft.com/cdo/configuration/smtpserverport") = 25 .Fields("http://schemas.microsoft.com/cdo/configuration/sendusing") = 2 .Fields("http://schemas.microsoft.com/cdo/configuration/smtpconnectiontimeout") = 60 .Fields.Update End With Set objCDOSYSMail.Configuration = objCDOSYSCon With objCDOSYSMail .From = EmailFrom .ReplyTo = EmailReplyTo .To = EmailTo .CC = EmailCC .BCC = EmailBCC .Subject = EmailSubject .TextBody = EmailBody If Len(EmailAttachment) > 0 Then .AddAttachment EmailAttachment On Error Resume Next .Send On Error GoTo 0 End With Set objCDOSYSCon = Nothing Set objCDOSYSMail = Nothing %>
```

The above code is called in `forgotPWD.asp` page which is below.

```vbnet
<% "" email address exists, send the associated password "" dim Mail, msg msg = "Thank you, " & rsPWD(0) & " " & rsPWD(1) & " for your inquiry!" & vbCrLf & vbCrLf & "Your Password for the Online Proposal Submission at Pace University is: " & rsPWD(3) & vbCrLf & vbCrLf & "Now you can access the system." MailObject Public Schema " CREATE MAIL " EmailFrom = "bmoy@pace.edu" EmailReplyTo = "bmoy@pace.edu" EmailBCC = "" EmailTo = var_email EmailCC = "" EmailSubject = "Pace IRB System Password" EmailAttachment = "" %>
```
6. Results

The scope of this project was reduced once the skill set of the team was fully understood. Initially, the team planned on using PHP as requested by the customer. However, the learning curve for this software was jeopardizing the project delivery. Once the decision to use ASP over PHP was approved, the project made headway. Add screen shots.

As planned, the system enables online submission of the IRB proposal with email notification to all necessary parties. The applicant can review the status of their proposal as well as make modifications. The approver can indicate any issues with specific data elements of the proposal and send email notification.

The result is an application that will significantly improve the turn around time for the submission and approval process for Pace’s IRB.

7. Skills and Knowledge Gained

One of the important skills gained from this experience is accessing a risk and determining a corrective action early enough as to not impact the project delivery. From the beginning of the project, there was apprehension of using software in which there was no experience. This began to affect the project timeline. The team was able to recognize this risk and take action.

Another skill learned was affectively working in a distributed team environment with various skill sets. With a team of three, each member’s assets were evaluated and a plan was created to appropriately divide tasks.

Although a project such as automating a document flow system may seem simple, with out proper planning, team management, project tracking, as well as risk management, it can easily fail. Each of those tasks was needed to implement the web-based system to facilitating Pace University’s IRB application process.

8. Conclusion

As time was spent designing and creating the system, ideas to further improve the process were formulated. To prevent scope creep and potentially missing the project deadline, these ideas were not incorporated. Below is a list of features future versions of the system may incorporate:

- Currently, only the person who submitted the proposal can login and view their proposals. A feature to add to this system would be the ability for the proposal’s Principal Investigator, Co-investigator or Faculty Advisor to login into the system and see all the proposals they are part of. The database design supports this feature.
- Another feature would be reporting capabilities. For example, the system could generate reports to show total proposals submitted by type, date, etc.
- Another option is to automate the “Study Renewal/Termination” request process. There is a form on the current IRB website the applicant uses to extend their study or terminate it. It would be easy to incorporate this option into the existing system.
- It is recommended to add a calendar displaying IRB Committee meeting dates on the IRB website. This would benefit applicants and help set expectations as to response time.

The new IRB system was written in known software enabling it to be easily maintained. The system created is expected to meet the customers’ needs and significantly improve the turnaround time for the application approval process. The system offers a single point of reference for both applicant and committee members thereby eliminating issues with version control of various documents.

9. References

http://en.wikipedia.org/wiki/Institutional_review_board
Appendix A

INSTITUTIONAL REVIEW BOARD

dedicated to safeguard the rights and welfare of human research subjects

Appendix B

INSTITUTIONAL REVIEW BOARD

dedicated to safeguard the rights and welfare of human research subjects

Appendix C

D2.7
Appendix D

To finalize and submit your application for review, please verify that you have completed all the required proposal information fully and accurately.

- Certificate of Completion of the NIH brief tutorial
- Proposal Info
- Principal Investigator, Co-Investigator and Faculty Advisor Info
- Checklist Questions
- Summary Statements

Please read the following statement carefully:

I have read the Pace University IRB policy on the treatment of human research participants. I will comply with the informed consent requirement, and I will inform the IRB if significant changes are made in the proposed study. I certify that all of the information contained in this proposal is true.

Submitting this form means that you affirm the statement above and will comply with the content. This counts as your legally binding signature.

FINAL PROPOSAL SUBMISSION