Pace University’s Web-Based IRB Application Processing System

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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. 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 describes the work involved to convert Pace University’s IRB application process from manual to an automated system. 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. This paper describes the work involved to convert Pace University’s IRB application process from manual to an automated system and is a continuation of previous work [3].

1. Introduction

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 [2]. 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. 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.

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 required on participant consent forms

The applicant must submit three copies of the proposal via mail or in person to Pace University’s NYC 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. It 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 approval 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].

3. IRBs at Other Universities

For the purposes of this project, a number of different IRB processes at educational institutions were investigated. They vary in complexity and automation. Harvard Medical School has multiple IRB Boards which meet monthly according to a published meeting schedule. Applications can be emailed or dropped off at the committee office. Researchers are encouraged to talk to a committee member before submitting an application, especially if the procedures are complex. There is an extensive website that includes instructions, forms, FAQs, tips, and contact information for the review board members. There is a tool called HIRBERT for the IRB Board members that facilitates the reviewing and tracking of applications and sending notifications [1].

The University of Pennsylvania, another top school for medical research, has a web based application process that appears similar to the IRB application currently under development, but the University of Pennsylvania online form prompts for detailed information about the study in the application. The form consists of fields for principal investigator, other investigators, campus department and address and funding sponsor. It provides an upload utility for the researcher to upload the required forms. After submission the researcher can see the application and the status. Based on the online instructions and FAQs, the application is new, fairly complex, and still requires manual steps if the forms were filled out incorrectly or certain information needs to be updated. The application email notifications get routed to the department chair based on values in the forms, and instructions on the site address complications with that process [5].

John Hopkins University has a different process for IRB approval. The applicants go through a pre-IRB review
process before getting routed to the IRB board for approval. This consists of a Prospective Reimbursement Analysis Review, a department review and a RSS review to determine if the application is complete. Some types need an additional step called a CFS review. Then the IRB is assigned to an IRB committee for review. There are 6 IRB review boards at John Hopkins University. The investigators use an application called eIRB to submit their applications online. The application form consists of a number of sections, including general information, which includes the principal investigator, the department and the title of the study. There are additional sections for site information, study location information and a section for the uploading of documents. After submission the researcher has access to a listing of all their active research projects and the status. They can submit changes to their projects after approval. The site also contains a wizard to help researchers prepare their applications, and determine if it qualifies for an Exempt or Expedited Review [2].

The University of Florida has four IRB boards that review submissions on scheduled bi-monthly board meeting dates. The process requires the submission of paper copies to the board offices. The researcher must pick up the approval paperwork from the IRB office. The following caution is on their IRB Website:

“The Administrative Office makes every effort to produce meeting correspondence, approval paperwork, etc as quickly as possible because we realize that researchers are eager to initiate their research. Please recognize that we have a large amount of correspondence to produce and that it takes a significant amount of time to respond to all of the items reviewed at the meeting. While some letters are available as early as the day after the meeting, it is not unusual for some paperwork to be completed up to a week after the meeting. We encourage researchers to send a representative to the meeting in order to expedite the approval process” [4]. The University of Florida could benefit by a Web based approval process to minimize the time delays created by the volume of paperwork needed.

4. Objectives of New Automated System

The requirements for the proposed automation of the application process have been defined by the previous work effort. 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 approach is to create a basic but robust application to submit a request IRB approval. It is limited by time and resources. The application will enable an applicant to submit their proposal, upload consent forms and other required documentation, and receive notification of receipt of the application. The create process captures a minimum of information about the proposal to enable the reviewers to identify the proposals, contact the principal investigator, and easily view key information about the proposal. The researchers, the IRB Coordinator, and the reviewers will receive email notifications for events in the application. Once submitted, applicants will be able to log into the system to view the status of the application. They will also be able to modify applications and resubmit. The reviewers will be able to log into the system and view all applications. They can make comments and email the applicant with those comments. They can also approve the application which will then send an email with that approval.

The application will protect the privacy of the applications by requiring researchers to register in the system and create their login credentials. 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

The software used in creating this application was PHP 5, SQL, and HTML.

5.1. Applicant Program Flow

The Pace University IRB system has 3 types of users: Staff, Applicants and IRB Reviewers. The initial screen prompts for user ID, and password. There is also a button to register as a new user. An authorized researcher user can request the password be sent to the email address used to register. Once an applicant user signs in, they will see either the create page or a page listing all proposals they submitted. Figure A1 (Appendix) shows the listing of proposals the applicant has submitted. For rejected proposals or proposals pending more information, they can update the necessary information and resubmit.

The applicant user can select a link to create a new proposal. This will bring him/her to the create screen to enter the required information. When the user is finished with the proposal, they will hit ‘Submit Application’ and an email will be sent to them and to the IRB committee as described in the previous section. Figure A2 (Appendix) shows the screen.

Once a reviewer or staff member signs into the system, they will see a page which lists all submitted proposals. These will initially include all proposals waiting for approval. Filtering functions will be available to change the view. From here, the user can view information about
the proposal, including the documents. Figure A3 (Appendix) shows this screen. Clicking on the description launches an edit window where the reviewer can send comments to the applicant and approve/reject by updating status. They will also be able to indicate that the proposal review is pending, waiting for additional information from the submitter. In all cases, an email is sent to the researcher(s). The IRB Co-coordinator can use this screen to assign a reviewer to an application by selecting from a drop down list of all reviewers in the admin table. Figure A4 (Appendix) shows this screen.

The application in total consists of five pages, the login page, the create proposal page, a page that list the proposals, a reviewer edit panel, and an applicant edit panel.

5.2. Database Design

The following tables have been designed:
- Authorized Users – stores the user id (email) and password for all authorized users of the system
- Projects – stores all the information submitted for a research project and its status. It also holds the current status of the application in the approval process, the reviewer assigned and the type of approval required
- Files – stores all the filenames and subdirectory for submitted applications by project number
- Admin – stores the user id (email) and password for all reviewers of submitted projects. Contains attribute for the person’s role in the process. Current roles are staff, chair and reviewer.
- Status - stores the available statuses for a submitted project.

6. Results

The application developed will offer a way to minimize the administrative work involved in the current process, which relies on paper copies sent in the mail or dropped off at the office. It will facilitate communications between the staff member, the reviewers and the researchers. It will give reviewers a quick view of the applications and easy access to the application packets and other required documents.

7. Recommendations for Future Work

The current Pace application packet sent to the IRB Board is a form that consists of many checkboxes that indicate the nature of the study. It also includes many form fields for other pertinent information, such as a listing of the investigators, funding of the project and contact information. Then there are areas that require descriptive text to detail the purpose of the study, the nature of the participants and the selection method for participants. Ideally these elements would entered in online forms and be captured in database fields. This would facilitate reporting, sorting and result in less manual effort spent managing on-going research studies.

The HIRBERT application developed for the Harvard University IRB Board provides extensive tooling for the IRB Board. The volume of research projects at Pace would have to be evaluated to determine the return on investment gained from the time and effort spend developing and maintaining this type of complex application for managing research project applications. As mentioned above, the University of Florida reports issues in maintaining information and managing changes in a complex web based application. The issues mentioned on the website cause delays and confusion in the IRB approval process.

The current application is designed to facilitate the initial application for approval. In future work, the application could be extended to handle other events that may occur while a study is active, such as revisions, renewals, and terminations.

8. Conclusion

The approval required by the federal government for research projects involving human subjects requires multiple pieces of documentation. In the processes investigated the review time can be weeks or months if the information is not submitted correctly or completely. Implementing a web based submission system can save time and labor for IRB reviewers. How extensive that system is would be best determined by the volume and complexity of the research projects being reviewed by the board.

9. References


Appendix

Figure A1. Researcher view of submitted applications.

Figure A2. Researcher screen to create an application for the IRB board to review.
Figure A3. Reviewers list of submitted applications.

Figure A4. Reviewer screen to update application status and send comments.