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Requirements Analysis and Design of IRB System

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Abstract: Institutional review boards (IRB) are established by institutions to protect (human) research subjects from abuse. Researchers are thus required to apply and obtain IRB ap- proval for any research initiative that involves human subjects. Currently, most USA institutions use paper-based or partially automated approaches for IRB application, review, and approval processes. This can be cumbersome, error-prone and usually add unnecessary workloads to researchers. Moreover, paper-based approaches can delay or reduce research output, especially during collaborative research projects if researchers are from different institutions. Web-based information systems can be developed and used to streamline IRB application and approval processes. Before such web-based systems can be developed, the requirements of the system have to be analyzed and designed. However, requirements analysis and design are usually very tedious and expensive project, which may discourage some institutions from implementing systems to support IRB processes. The aim of this paper is to contribute a set of requirements and systems models that can be customized and re-used, by other institutions, to develop IRB Systems. Accordingly, we provide the following models, use case, feature tree model, and network diagram. In addition, we discussed our experiences and systems analysis principles we adopt to make this project a success. We believe that the experiences we share and the models we provide in this paper can inform practice and advance the knowledge of web-based information systems development. Re-using existing requirements and designs can also help to reduce the amount of time and cost required to develop similar systems.

Keywords: Functional Requirements, Feature Tree Model, IRB, Web-based System, Information Systems and Technologies, Design Models

1. Introduction

Universities and colleges (hereafter referred to as institutions) in the United States, especially those that conduct research, are required by federal law to constitute institutional review boards (IRB) [28]. The primary objective of IRB, according to Lincoln and Tierney [19], is to protect (human) research subjects from abuse, violation of right, harm, and deception. Therefore, it is mandatory to apply and obtain IRB approval for most research that involve human subjects. Activities involved in IRB application may have little or no variations across institutions, but generally involves a long, cumbersome, tedious, and time consuming process [18, 28]. These usually add unnecessary burden to faculty and have the potentials to delay and even reduce research output [5, 20, 30]. The same also applies to the review and approval processes. These are even exacerbated when the application and approval processes are carried out manually i.e., paper- based. Unfortunately IRB application, review and approval processes are largely paper-based in the USA [12].

Experience shows that in a typical paper-based IRB application process, the principal investigator (PI) would download relevant forms from the institution's website, complete the forms, attach supporting documents, scan and mail the forms to co-investigators (CI) to review and sign. The CIs would then print the forms, sign the required pages, scan and mail them back to the PI. Afterwards the PI would submit the forms to IRB for review and approval. In institution where scanned signatures are not allowed for IRB applications, the PI and CIs would sign and send the forms through snail mail, which normally involves delays due to longer delivery time. Further delays can be encountered in

cases where the PI and CI are from different institutions or mult-isite institutions, and can be worst if the collaborating institutions are from different countries. After completion and signing, the forms are submitted together with supporting documents to the institution's IRB. Then the PI and CIs have to wait for IRB to convene a meeting, review their application and take decision. Empirical studies [18, 20, 28] have confirmed that the time range from application to approval, espcially in paper- based approaches, is normally between 40 to 103 days. These can even be longer if IRB reviewers require additional in- formation or more supporting documents from the PI and CIs. In addition to delaying and reducing research output, paper-based approaches are generally known to be error- prone, inaccurate and ineffective, with a higher susceptibility to loss, inconsistency, and malicious tampering. Hence, there is a general consensus by researchers such as Silberman and Katherine [27], Lincol and Tierney [19], Bian et al [2], and Gardy [11], that the current approach to IRB is inefficient, thus the need for web-based systems support.

Web-based systems can be developed and used to streamline IRB application, review, and approval processes [2]; support process improvement, and in addition provide scope for inno- vative advances in IRB process. For instance, web-based sys- tems features such as 'instant notification' can be implemented and used to inform PIs and CIs about the progress of their IRB application and thus enhance timely and accurate communi- cation. More so, database systems can support effective IRB data management, generate useful reports about IRB practices, as well as ensure data privacy and security. Furthermore, mobile technologies and devices can be leveraged to design ubiquitous IRB systems; while data mining and machine learning techniques can be applied to derive useful intelligence about research directions in public and private institutions.

Despite the potential benefits and promises of web-based systems, most institutions in the USA lack web-based systems for IRB application and approval processes [12]. In very few cases, where such systems exist, they are normally partially automated i.e., their functionalities are limited to uploading and downloading IRB forms only, while other activities and processes are paper-based. Few others such as irbnet1 are usually built for generic and commercial purposes. Their commercial nature can make them too expensive and difficult to afford and maintain by most institutions, especially smaller institutions with limited funds. Equally, their generic nature limit them to 'one size fits all' systems approach. But most institutions would need 'custom made' IRB systems to meet their individualize research needs and organizational context, therefore such systems are hardly applicable. Moreover, in other institutions, on-going research experiments and results are usually classified until they are concluded and published. For such institutions, systems, such as irbnet, which are owned and managed by external organization may be problematic to use due to concerns about research data management, protection, and privacy.

Web-based systems are usually developed from predefined functional requirements *i.e.,* the functionalities (functions), functions, behavior, and features that should be implemented in a web-based system [22, 23, 32]. For instance, an integrated attendance monitoring system (IAMS) has been developed from the predefined requirements presented in [32]. Hence, the first step to- wards developing web-based information systems is usually to develop the systems requirements [33]. In this paper, we report the experiences and techniques used in our just completed 'requirements development project' for a web-based IRB sys- tem. In addition, we used feature tree model and use case diagram to identify a set of re-usable functional requirements for a web-based IRB system. We hope that our experience as well as the requirements models we provide in this paper will inform practice and advance knowledge of web-based systems development.

The rest of this paper is organized as follows: In the Section that follows, we provide a description of our case study i.e., the institution where we conducted the 'requirements development project' of the IRB system. Please note, this institution has requested that its name remains anonymous, hence we will use 'Institution X' instead of the real institution's name. The review of related work is presented in Section III. This is followed by Section IV where we discussed the requirements elicitation techniques we used for this project. In Section V we used feature model to capture and describe a set of re-usable functional requirements for an IRB system. The user require- ments and systems architecture are discussed in Section VI.

In Section VII we discuss how we validated the identified requirements, and concluded our paper in Section VIII.

2. The Case Study

Institution X is a private co-education university in north-easter section of the USA; offering associate's, bachelor's, master's, and doctoral degrees and certificates. Currently, the total enrollment is 4,410. Institution X is organized into three academic colleges namely: College of Engineering and Business, which includes a School of Business Administration; College of Humanities, Education and Social Sciences; the College of Health Professions and Sciences. Each college has a dean as its head of administration. Currently, there are 258 full time academic staff (faculty), excluding adjuncts, who, in addition to teaching, are expected engage in research initiatives and produce scholarly publications yearly. Most faculty, especially, those in College of Health Professions and Sciences, use human beings as subject of research, and are thus required by federal law to apply and obtain IRB approval.

Consequently, Institution X has establish an Institution Review Board (IRB) Committee in compliance to policies established by the Department of Health and Human Services (HHS). The IRB Committee of Institution X has 11 members including the Committee Chair and Secretary. The Commit- tee's main responsibility is to review and

reject or approve all research proposals that include the use of human subjects for research whether conducted by faculty or students. The IRB application and approval processes in Institution X are paper-based and follows the description given in Section I (2nd paragraph). To streamline its IRB processes and eliminate delays in research output, Institution X has initiated a 'web- based information system development' project to automate their IRB application, review, and approval processes.

This project is under the jurisdiction of the vice president of academic affairs, in Institution X, who hereafter referred to as the Client or Project Owner. Institution X has divided this project into two broad phases, namely: Requirements Development Phase and Implementation Phase. The authors of this paper are responsible for the 'Requirements Development Phase' of the project. Thus the focus of this paper is to report our experiences, techniques and models used during the Requirements Development Phase.

3. Review of Related Work

Institutional review board (IRB) are charged with providing an independent evaluation of research involving human sub- jects to ensure that they comply with predefined ethical stan- dards. For research that do not comply with these standards, IRB can also provide suggestions on how to improve the stud- ies to ensure ethical compliance. Over the years, the number of IRBs across the United States and around the world have increased rapidly due to growth in the number of research on human subjects [12]. As a result, several research efforts focus on investigating how different IRBs practices and processes impact on human subject research from various perspectives. One these perspectives is investigating the variability of IRB processes across institutions [28, 15, 20, 6]. The findings from these publications revealed that IRBs processes are not streamlined. In addition, there are significant variations on how IRBs handle human subject research at various institutions. For instance, Dziak et al [6] observe that" lack of standardized and structured application forms across different IRBs causes inefficient and inconsistent proposal reviews and cumbersome workflows."

Other research such as [27, 9, 11] analyze the problems and challenges facing IRB practice. Among the identified problems and challenges are duplicative review process, in- efficient communication among stakeholders, and variable decisions times across institutions [12, 27]. These problems can be traced to the prevalence of paper-based approaches and partial automation to IRB application and approval processes. Partially automated IRB systems can be used to upload IRB forms to institution's webiste, and also allow applicants to view and download these forms online. Beyond these, other activities such as completion, submission, review, and approval of application forms follow the same cumbersome, tedious and time consuming paper-based approach [12]. In addition, partially automated IRB systems have limitations, particularly, in data processing and analysis, as well as information sharing between various IRB stakeholders [12].

Generally, researchers [30, 27, 28, 15, 20, 6, 9, 11] acknowledge and agree that IRB application and ap- proval processes are burdensome, and, in many cases, have delayed research initiation and output. Hence the need for information systems and technology (IST) support as well as full automation. However, there are very few research and publications that have considered the design, development and application of IST to standardized and streamline IRB application, review, and approval processes. As a step towards bridging this gap, He et al [12] proposed a domain analysis model for standardizing the information elements within the IRB processes. This model can be used to integrate clinical research workflow with other clinical research informatics systems to improve the IRB application throughput using computer-assisted decision support. Although this research is a step in the right direction towards developing a domain model for standardizing the IRB process, its applicability is mainly limited to the health domain. This is similar to the Clinical Research Administration (CLARA) platform proposed in [2], whose functionalities and uses are limited to the medical domains. In contrast, we aim to develop and provide IRB systems requirements and design specifications that would be applicable across all domains.

In another attempt to streamline IRB process through IST, Friedman et al [8] described the procedure involved in convert- ing an IRB application process from manual to an automated system. But this does not provide functional requirements or design models that can be used by other institutions that desire to develop IRB systems. Some other studies focus on investigating how various research projects conforms to the IRB standards with respect to protecting privacy of human subjects in specific domains such as in the medical domains.

For example, Chen et al [4] proposes an intelligent privacy- preserving administration tool (iPAT) designed to prevent the privacy of research subjects from being disclosed unintention- ally. Although the contributions made by existing approaches can be considered to advance IRB practices and processes, they normally provide restrictive usage due their focus and applicability on a particular domain e.g., health and medi- cal domains. More importantly, none of the existing studies provide functional requirements and design models that can be re-used by information systems designers for developing IRB systems. We believe that a web-based information system can help to streamline and standardized IRB processes, and provide effective means of communication together with IRB data management, privacy and protection. More so, web-based systems can relieve administrative burdens, reduce or eliminate delays in research output, and provide a paperless method for application, review, and approval of IRB [2]. However, the development of such systems can be possible if there are re- usable functional requirements and design models to facilitate systems implementation.

4. Requirements Elicitation Technique

One of the challenges we encountered during the requirements development phase was to decide on suitable requirements elicitation technique. Requirements elicitation technique is any activity carried out to ensure that the needs and concerns of systems stakeholders are well identified [14, 29, 13]. Stakeholders needs and concern are subsequently transmuted into requirements (functional and user) and design models to be encoded into the system [14]. There are various require- ments elicitation techniques that can be used for web-based information systems, these include brainstorming, interviews (formal and in-formal), workshop, document analysis, among others [14, 13, 29]. Requirements elicitation technique can have impact (positive or negative) on the functions, behavior, operations, and quality of a web-based system.

Therefore, it is important to identify and use a suitable elicitation technique. From our experience, there is no silver bullet or 'one-size fit all' approach for identifying and selecting elicitation techniques for web-based information systems. Instead, the selection of elicitation technique are based on factors such as organization context and context, scope of the project, and available resources. For instance, Workshop and Brainstorming may not be suitable in an organizations where freedom of expression is not encouraged and staff are usually not expected to express their opinions. Similarly, Document Analysis may be difficult in organization that lack systematic approach to recording keeping, filling, and documentation.

To overcome the challenge of identifying and selecting suitable elicitation techniques, we first identified our aims or goals *i.e.,* what we intend to achieve during the elicitation. Afterwards, we identified and studied requirements elicitation techniques from extant publication [14, 13, 29]. Finally, we map each elicitation technique to our aims and select those that closely align to these aims. The result is shown in Table 1. This Table shows the four requirements elicitation techniques that closely aligns to our aims stated in the right side of Table 1. These techniques include focus group, brainstorming, and observation. We discuss these in the following paragraphs. is to identify the stakeholders to be invited for the session. The term 'stakeholder' is broadly defined in [21] to include any human entity that has interest or a stake in the system, including the project owner and users of the system. We use the stakeholder nomination 2 approach to identify and select relevant stakeholders that attended this focus group session [24]. In this approach, we asked the Client to nominate other relevant stakeholders that should be invited to the focus group session. Stakeholders who were nominated and attended the focus group session include the institution's IRB chair, IRB members, academic affairs and administration representatives, dean of colleges, and the institution information technology experts.

Table 1. *IRB Systems Elicitation Process.*

Elicitation Techniques	Aim
Focus Group	To identify stakeholders, their key concerns, needs, and actions and roles they might perform in the IRB system
Observation	To understand organization con- text, processes, and user activities for the IRB system
Brainstorming	To collate and analyze the informa- tion gathered in focus group and observation, and transmute these into systems features and visual requirements
Document Analysis	To understand the input and out- put information (business entity or data) in an IRB application, review, and approval process

This focus group, which lasted for one hour, was held in the Client's conference room with a total of 10 attendees. During this session, we (authors) first introduced the objectives of the group and the IRB systems visions. Afterwards, attendees were given an opportunity to discuss the problems and challenges with the current IRB paper-based approach. Other activities carried out during the sessions include giving stakeholders the opportunity to express their concerns, discuss systems features and functions, identify other potential users of the system, and state how they would like to use the system. Finally there was a 'question and answer' session. The project team made notes of the stakeholders concerns.

We used the observation 3 method of requirements elicitation to complement the requirements gathered during the focus group session. This method involves studying/learning how prospective users of the system perform their work, to gain bet- ter understanding of organizational context and processes [10, 25, 3]. At the time of requirements elicitation, only six (6) faculty members were completing IRB applications. We observed and took note of the processes involved completing and submitting IRB forms as well as obtaining approval. Our observation was active, hence we interacted with the users and asked questions about the types and contents of the forms, supporting materials that can accompany the forms, those responsible for completing each section of the forms, submission process, etc. The review process and approval process are carried out by the IRB board members and require some confidentiality. However, the chair and some members of the IRB board provided insight on the review and approval pro- cesses. In addition, to brainstorming, we also analyzed existing IRB application forms, approval notices, submitted forms, reviewed forms, and supplementary documents uploaded to support applications.

Finally, the project team organized a brainstorming session to further analyze the information collected during the focus group session and observation. The project team is made up of the project manager, requirements/business analysts, and programmers. The brainstorming eliticitation technique support the discovery of creative ideas about the requirements of the system [16]. During the brainstorming session, members of the project team structured the stakeholders needs and other collected information into systems features and functions at various levels of

granularity. Furthermore, we identify key user activities that each user can perform in the system and organized these into use-cases. The identification of key systems components, and architecture also took place during the brainstorming sessions. In the sections that follows, we use visual models to specify and describe functional and user requirements, as well as systems architecture for a typical IRB system.

5. Functional Requirements

The functional requirements identified during the requirements elicitation process are described using the feature tree model (FTM) shown in Figure 1. A feature tree model is a visual model that provides a means to capture, structure and describe software/systems requirements at various levels of hierarchy [7, 26, 17]. One major advantage of a feature tree model is that it can be used to organize and describe systems requirements at an increasing levels of details or granularity [7]. As shown in Figure 1, we structure the proposed requirements into three (3) main levels of granularity viz, L1 or main features, L2 or sub-features, and L3 or functions. The main or L1 features are the top level systems functionalities that encapsulate other functions. In most cases, L1 features are abstract functionalities i.e., they may not be directly implemented in the system. We have identified three (3) main features, represented with purple rectangular boxes as shown in Figure 1. These include 'IRB Application', 'Accounts Management', and 'IRB Approval'. Each of these main features include L2 or sub-features, written in 'olive green' colors in Figure 1. L2 features can be implemented as menu containing specific and related systems functions or L3 features. For instance, the 'Application Review' sub- feature, see the 'Applications Manager' main feature, can be implemented as a menu that contains functions such as 'review application, request additional information, assign reviewer', and so on. The sections that follows describes each main feature, its sub-features and functions, where necessary a table can be used to describe the uses of specific functions.

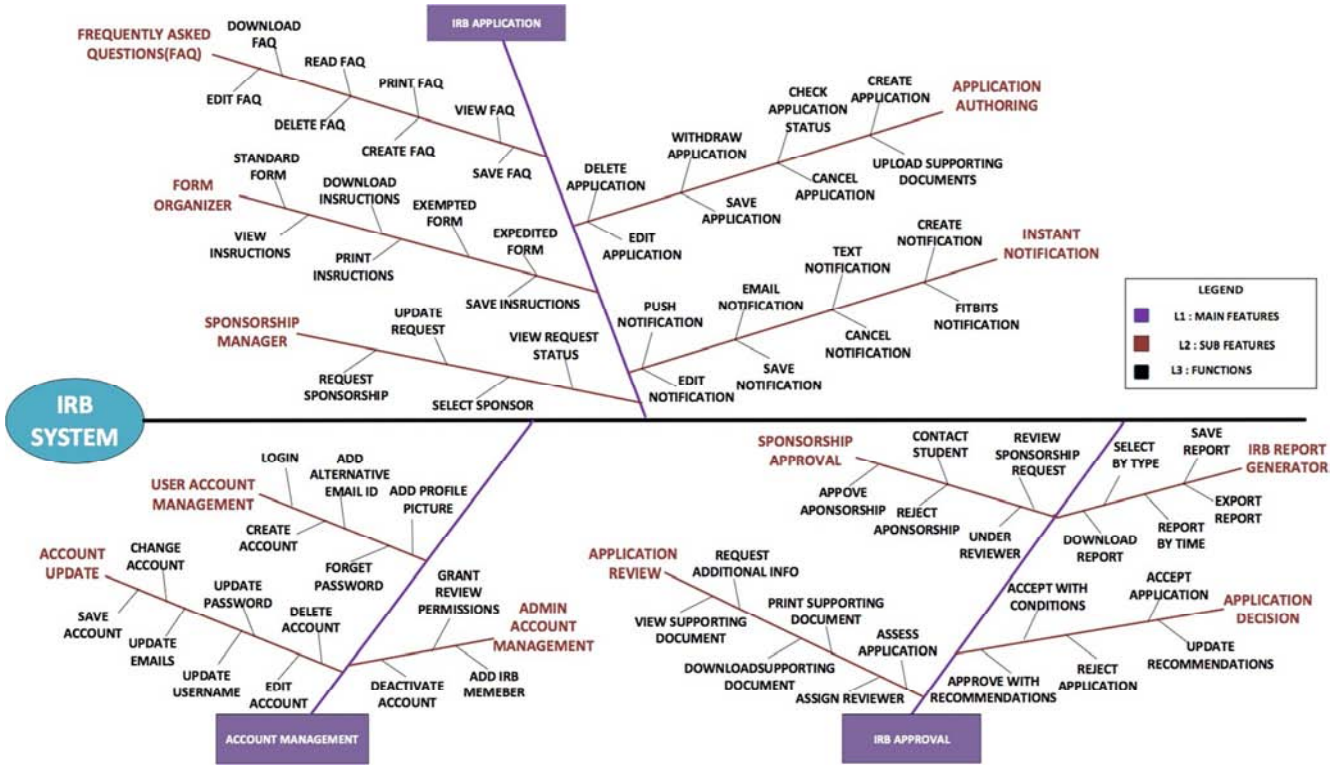

Figure 1. *Feature Tree Model Showing Requirements That can be Implemented in a Typical Web-based IRB System.*

IRB Application

This feature provide systems functionalities that can be used to enhance IRB application process. It includes five (5) sub- features namely 'application authoring', 'instant notification', 'sponsorship manager', 'form organizer' and 'frequently asked questions'. The 'application authoring' sub-features include specific functions that can be used to create, update and submit IRB application as well as upload supporting documentations. The 'instant notification' sub-feature include functions such as 'create notification', and 'select notification option', which can be used to provide timely notification about application, review, and approval processes. This can be used to streamline communications between stakeholders during IRB processes. For instance, applicants should be notified in real time when their application changes from 'submitted' to 'under review. The 'form organizer' can be used to store various IRB forms e.g., standard form and exemption form, so that applicants can easily identify and select the forms that are most suitable for them. In most institutions, students are required to request and get approval from a faculty or staff before they can apply and obtain IRB approval. The 'sponsorship manager' sub-

feature provide specific functions to automate this process and provide functions that can be used by students to request faculty sponsorship. In Table 4, we presents each sub-feature in the 'IRB Application' main feature, and describe the uses of their specific functions.

Account Management

The account management feature describe sub-features and functions that can be used to manage and update both user and IRB admin accounts. It has three (3) sub-features which include 'user accounts manager', 'admin accounts manager', and 'accounts update'. The 'user account manager' includes specific functions such as 'create account' that can be used to create account and access the system. The 'admin accounts 4 Please Note: In other to optimize space, some basic functions such as edit, save, print, etc., shown in the FTM are not included in the third column of these tables. Instead they are mentioned in the last column manager' can be used to perform admin functions such as 'add IRB member' and 'deactivate account'. Finally the 'account update' provide general update functions that can be useful in updating accounts. More information about the uses of specific functions can be found in Table 3.

Table 2. *IRB Application Functions and Their Uses.*

Main feature	Sub-Feature	Function	Use/Description
IRB Application	Application Authoring	'Create Application'	This function can be used to create and edit IRB application
		'Upload Supporting Document'	Provides an upload or 'drag and drop' function for uploading docu- ments to support IRB application
		'Check Application Status'	Allow users to check the status of their application, e.g., submitted, under-review, withdrawn, approved, etc.
		"Update Application'	Provide general update functions such as cancel, save, and edit application
		'Withdraw Application'	Allow users to withdraw or delete a submitted application
	Instant Notification	'Create Notification'	Can be used by IRB admin to create notification message and select the type of notification e.g., approval notification.
		"Select Notification Option'	Provides various options of notification, e.g., e-mail, text, push notifi- cation, and fitbits, and allows users to select from any of these.
		'Update Notification'	Provides generic update functions such as edit, save, and cancel
	Sponsorship Manager	'Select Sponsor'	This function allows students to select a sponsor from a list of research active faculty that have been approved by IRB to sponsor students' research
		'Request Sponsorship'	This function provides a form that allow students to describe their re- search and request for a faculty who can sponsor their IRB application
		'View Request Status'	Can be used by students to view the status of their sponsorship request
		'Update Request'	Provide general update functions such as edit and delete sponsorship request
	Form Organizer	Select Form	Used to organize various forms such as standard, exempt, and expe- dited forms, used for the IRB application process, so that users can easily select forms that are relevant to their application
		'View Instruction'	Allow users to view, download, save, or print instructions for com- pleting IRB application.
	'Frequently Asked Questions'	'View FAQ'	Allow users to view, download, read, or print frequently asked ques- tions.
		'Update FAQ'	Can be used to create, edit, and delete frequently asked questions

Table 3. *IRB Accounts Management Functions and Their Uses.*

Main feature	Sub-Feature	Function	Use/Description
Account Management	User Accounts Manager	'Create Account'	This function allows users to create account in the system by com- pleting and submitting a short application proforma
		'Add personal details'	Users can use this function to add optional personal details, such s profile picture, alternative email, etc., to their accounts.
		'Forget passwords'	Used to re-set password if users forget their password
		'Login'	Used to access/log into the system
	Admin Accounts Manager	'Add IRB Member'	IRB chair or admin can use this function to add a new IRB member
		'Deactivate Account'	IRB chair or admin can use this function to remove/deactivate the account of IRB members who have completed their year of service
		'Grant Review Permissions'	The chair or admin can use this function to grant review permission to a new IRB member.
	Account Update	'Delete Account'	Allow users to delete their account if they no longer wish to use the system
		'Update Account'	Allow users to edit, save, and change account details such as username, password, e-mails, etc.

IRB Approval

This feature include sub-features and specific functions that can be used to support IRB review and approval processes. Most of the functions included in this feature can be performed by a designated administrator such as IRB chair or member. Its sub-features includes 'application review' which provides functions that can facilitate the review of submitted IRB application; the 'application decision' sub-feature can be used to enhance decision and make recommendations on each ap- plication;

and 'sponsorship approval' which provides functions that can be used by faculty to review and accept students' sponsorship request. In addition to these, the 'IRB report generator' include functions that can be used to run reports and generate useful information from stored IRB data. The uses of specific functions for each sub-feature have summarized in Table 4.

Table 4. *IRB Approval Functions and Their Uses.*

Main feature	Sub-Feature	Function	Use/Description
IRB Approval	Application Review	'Assign Reviewer'	Can be used by IRB chair or admin to select and assign reviewers for a given submission
		'Request Additional Information'	Allow reviewers to contact principal investigators, if need be, to request for additional information to support application
		'Assess Application'	Allow reviewers to provide comments and ratings on a each application
		'View Supporting Document'	Can be used by reviewers to view, download or print supporting documents submitted with each application
	Application Decision	'Take Decision '	This feature allows reviewers to select decision, about an application, from a list of options (e.g., accept, reject, accept with conditions, or approve with recommendations).
		'Update Recommendations'	This function is optional, and may be used if the decision selected by a reviewer is "Approve with Recommendations"
	'Sponsorship Approval'	'Review Sponsorship Request'	Can be used by faculty to review and assess sponsorship requests from students
		"Contact Student'	This feature allows faculty to contact, if needed, and request for additional information to support decision about sponsorship request
		'Update Approval Status'	Used by faculty to update the status of the sponsorship request. Example of status can be approve, under reviewer, reject, etc.
	IRB Report Generator	'Select Format'	This function can be used by IRB chair or designated member to select IRB report format e.g., bar charts, tabular, etc.
		'Report by Time'	This function allow IRB chair/admin to generate IRB reports by time, e.g., number of IRB applications per quarter, semester or year.
		'Export Report'	Can be used to export reports to other formats, e.g., excel, pdf, etc.
		'Download, save, print'	These functions can be used to download, save, or print the generated report
		'Select by type'	This function allow IRB chair/admin to generate IRB reports by types, e.g., rejected, approved, withdrawn, etc., IRB applications

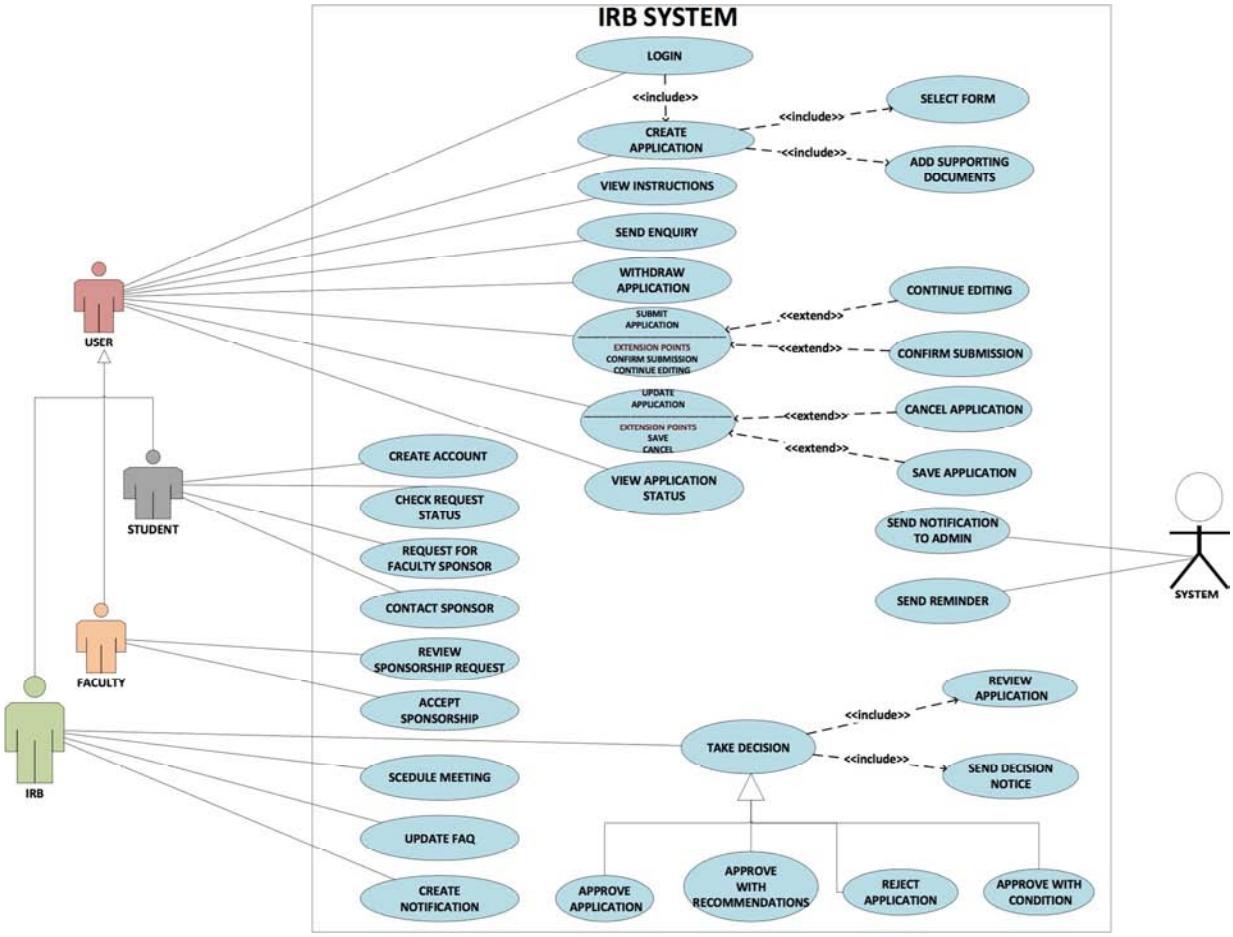

Figure 2. *Use Case Model for a Typical Web-based IRB System.*

6. User Requirements and Systems Architecture

The use case model shown in Figure 2 is used to capture the high level user requirements. A 'usecase' model is known to provide means for describing user requirements by showing the activities (usecases) performed by each actor (user) in a proposed system. In this figure, 'usecases' are represented as ellipse while actors are represented with 'stick-like' figures. In our 'usecase' model, we apply the concept of 'usecase gener- alization and inheritance' to show the 'usecases' that can be performed by a general user and specialized users. As shown in Figure 2, specialized users such as students and faculty can (inherit) or perform same activities as a general user, e.g., 'create application' and 'submit report'. However, some 'usecases' can only be performed by specific users, e.g., only IRB member can 'take decision' on a submitted application. An actor called 'system' is an autonomous program that is responsible for providing instant notifications and reminders about the application, review, and approval processes.

A typical systems architecture for a web-based IRB system is shown in Figure 3. This is a generic 'client-server' architecture that can be customized and re-used by other institutions. In a client-server architecture, remote computing devices called clients can request and access shared resources from a server through a communication network, usually the internet. A server is a higher processing computer that manages shared data and other resources [1]. As shown in Figure 3, client computers from any user e.g., university professor, can be used to request and access information through the internet. A 'domain server' can be used to resolve domain names and convert them to internet protocol (IP) address readable by a web-hosting server. The information stored in a database server can be accessed through the web hosting server.

7. Requirement Validation

The last steps in our Requirements Development Project is to validate the functional and user requirements we have identified. One important goal of this requirements validation exercise is to ensure that the right web-based system will be developed [31]. In order words, to ensure that the corresponding IRB system will be able to satisfy user objectives and stakeholder needs. One efficient and effective method of validating requirements of a web-based system is the 'Prototype Method', which entails building a functioning model (prototype) of the system using the identified requirements [31]. There are various platforms that can be used to build prototype for a web-based system. Some examples of these include MAMP/WAMP5, Axure RP6, Invision7, and Adobe Experience Design CC8. After reviewing these platforms, we discovered that the MAMP platform can be used to integrate client-side (web-pages) to the server-side (dynamic database) of a web-based system, hence we used (MAMP) to build our prototype.

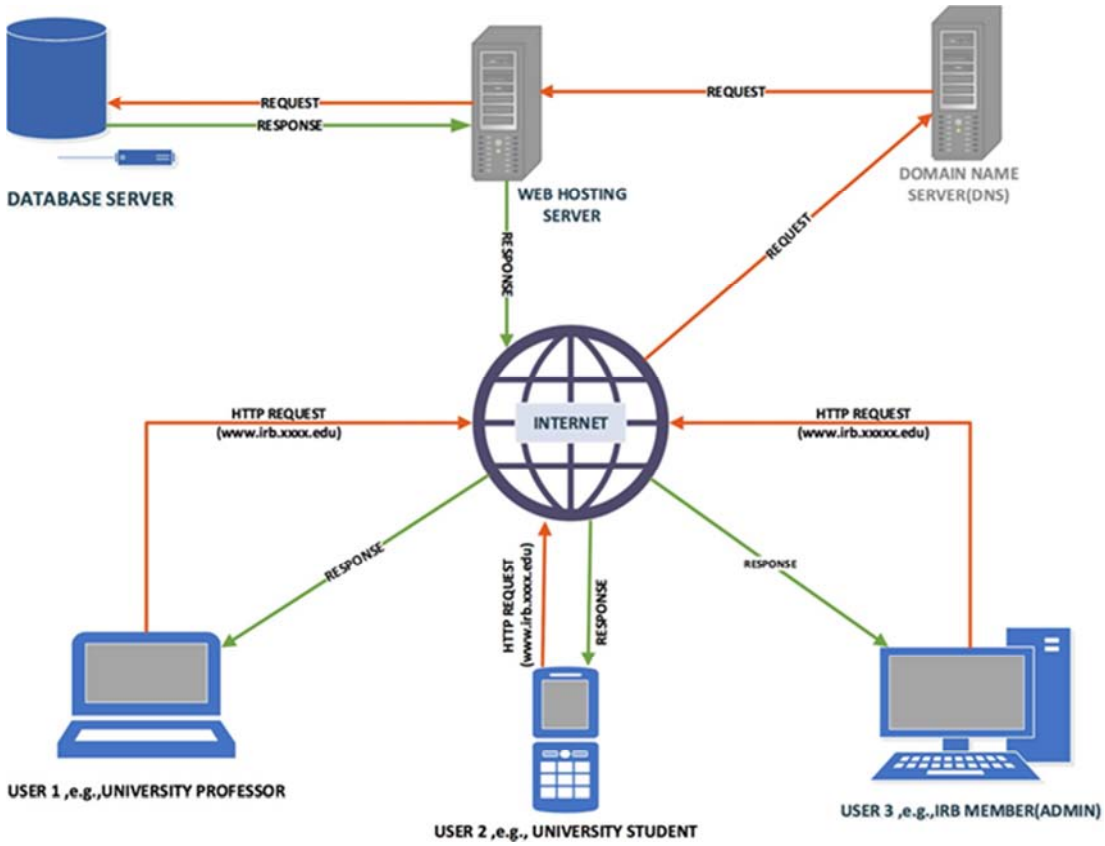

Figure 3. *Systems Architecture for a Typical Web-based IRB System.*

We used a combination of HTML, Java Scripts, and CSS to built the prototype of the client side, while the database was developed with mySQL. Afterwards, we used Php to integrate the client side with the server side. Figure 4 shows the prototype homepage of the IRB system. Note: To maintain anonymity, the logo and other information that show details of Institution X were removed from this and other Figures of the prototype. This Figure shows the prototype of func- tional requirements, such as 'Login and 'Create Account' (Register), captured with the feature tree model in Figure 1. Similarly, the prototype of other functional requirements such as 'submit application', 'view sponsorship request' and 'upload supplementary materials' are shown in Figure 5. Due to space, prototypes of other functional and user requirements are not shown in this paper, but can be made available upon request.

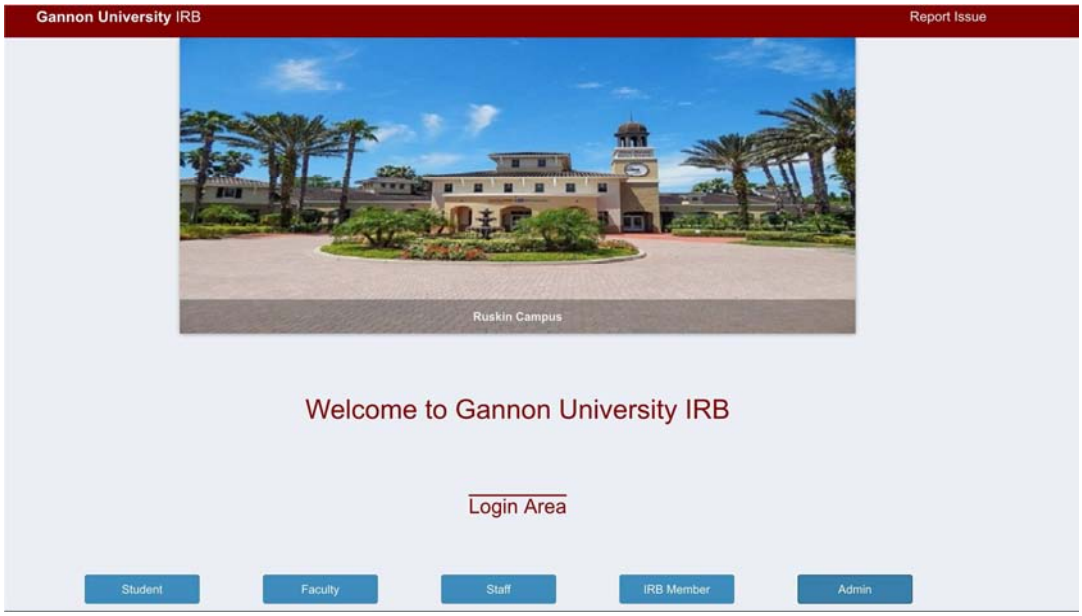

Figure 4. *Implemented Home Page of the IRB Software.*

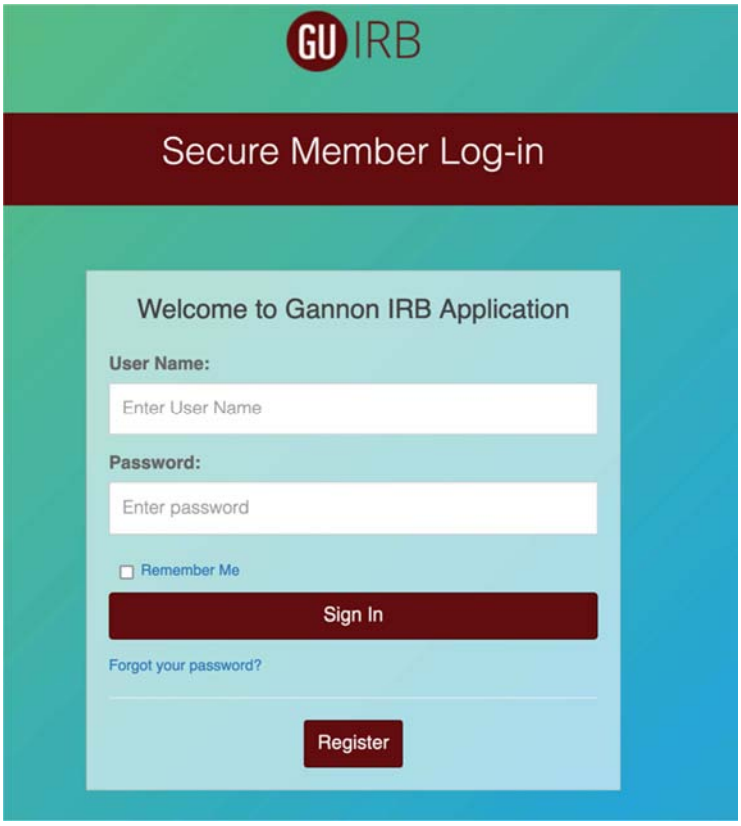

Figure 5. *Implemented Registration Page for the IRB Software.*

8. Conclusion

Federal laws, in the USA and other countries, require researchers to apply and obtain approval from institutional review (IRB), particularly for research that involves the partic- ipation of human subjects. IRB is thus an important academic committee that provide oversight functions and ensure that research comply to predefined ethical standards. However, existing research show that the processes involved in apply- ing, reviewing, and approving IRB application are largely paper-based, or at most partially automated. As result, IRB processes are becoming cumbersome, ineffective, and time consuming. These add additional and unnecessary workloads to researchers and have potentials to reduce research output and discourage the pursuits of research projects. Existing IRB research and publications focus on identifying these problems, and analyzing variability in IRB approval processes across institutions. They also recognize the need to streamline and automate IRB processes using information systems and technologies. However, generally, they neither develop such systems or provide re-usable requirements and design models that can be used to develop such systems. In few cases where systems exist, they are either partially automated or limited to a specific domain, usually the health domain. Hence the prevalence of inefficient and time consuming paper approach. This paper reports the methods and techniques we used to develop requirements of a web-based IRB system for an institution in the USA. One major challenge in this project was to engage stakeholders and identify their needs to be encoded in the system. Stakeholders engagement and involve- ment are critical to web-based systems development project, yet difficult to attain. This project took place in a busy and academic oriented site, where stakeholders are always busy and thus the difficulty in getting them involved in the project. For instance, it was difficult to find meeting time that fits into stakeholders busy schedule. To overcome this type of challenge, practitioners should consider alternative requirements elicitation techniques that can allow stakeholders to participate at their own pace and time. For instance, instead of scheduling face-to-face meetings at busy hours, multimedia and social network technologies such as Skype and Whatapps, can be used as alternative methods of meeting. With such technologies, requirements elicitation meetings can held at flexible times, e.g., after normal working hours, that fits into stakeholders schedule. Moreover, questionnaires and survey tools such as Survey Monkey, can be used as alternative to interviews. Yet, in so doing, practitioners must weigh the trade-offs, pros, and cons of each elicitation techniques against factors such as organizational culture.

The aim of this paper to support the design, analysis, and development of a web-based system that can be used to streamline IRB application, review, and approval processes. To do so, we share our experiences and provide design models and functional requirements we developed in our just completed Requirements Development Project of a web-based IRB system. We anticipate that these functional requirements and design models can be customized and re-used by other institutions to implement IRB system; thereby reducing the significant amount of cost, time, and resources expanded in de- veloping requirements for web-based systems. We understand that institutions have individual research needs and custom IRB processes. Therefore, the requirements and design models provided in this paper are not intended to be prescriptive. Instead, institutions can customize and re-use them to meet their specific research demands. In so doing, they reduce the amount of work and resources that would have otherwise expanded in requirements development and modeling.

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