ABSTRACT

A Study of a Workflow Management System in Higher Education

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The Online Protocol Submission system is web-based workflow management system designed and implemented by Information Technology Services and the Office of the Vice Provost for Research at Baylor University. The system is secure and modular. The system automates certain processes in an effort to streamline the protocol procedure of the Institutional Review Board in preparation of the influx of protocols from Baylor University's vision to become a leading research institution. This project is a building block in moving the Baylor culture into technological innovation by replacing paper-laden processes with automated processes. This paper will describe the design process of the Online Protocol Submission system and examine its ability to handle the increase in workflow of the IRB.

A Study of a Workflow Management System in Higher Education

by

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A Thesis

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ACKNOWLEDGMENTS

This thesis emerged from years of programming performed since I came to Baylor University. On this project, I worked with many people whose contributions lead to the completion of this project. I learned many considerable lessons in working on this project. This is the first project where I caught a glimpse of the administrative side of a university and its function.

First, I would like to thank the Office of the VPR and the IRB Committee for their involvement and cooperation with this project. I would especially like to thank Sherri Honza who encouraged me to stay on track in her own little way during the tough parts of this project. I would also like to thank Rona Stefka and Sandra Harman who provided valuable insight into the behind the scenes workings of the Institutional Review Board. Dr. Matthew Stanford is the IRB chair and volunteered to be on my thesis committee. I would have been lost and hopeless during the project and this thesis if it was not for him. Without their help and guidance, this project would have never developed.

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To my family and friends who have supported
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trials and tribulations through the years

CHAPTER ONE

Introduction

Part of Baylor University's vision to become a leading research institution includes growth in the sciences by means of building new facilities, hiring new faculty, and creating new departments. These developments promote an increase of research throughout the campus. Some of this research requires the study of human subjects. The Institutional Review Board protects the safety and proper treatment of human subjects in research.

In 2001, The Office of the Vice Provost for Research determined that the current workflow process of the Institutional Review Board was inadequate to handle the inevitable influx of protocols due to the 2012 Vision. It is necessary to automate the process to assist with the expected workload. A computer-supported cooperative work will solve the problem. The Online Protocol Submission system is a workflow management system designed by Information Technology Services and the Office of the Vice Provost for Research at Baylor University.

Technological innovation has begun to move most paper-laden processes into electronic processes. There are many different approaches to automating business processes. A major task of this project was to determine how to change the Baylor culture to accept a computer-supported cooperative work. The project succeeded through social engineering by taking a business process reengineering approach. Like any

project, there is always opposition to change. The method used to combat this opposition can sometimes make or break a project.

This paper will give insight into the procedure of constructing a workflow management system in higher education. The paper starts with a description of the design process and approach used to complete the automated system project. It will look at the features expected from the automated system as well as the expectations of the users and IRB committee. The paper finishes with an examination of the automated system's ability to handle the increase in workflow of the IRB by analyzing the new processing times of each of the processes automated. Changing the culture of a university is a daunting task. Similar institutions should use this paper in deciding if a similar approach is the solution to their technological innovations.

CHAPTER TWO

Definitions

Institutional Review Board

As part of the Department of Health and Human Services, The Office for Human Research Protections has set forth a policy for the protection of human research subjects. The Institutional Review Board is a committee at an institution designated to monitor the ethical use of humans in research. The OHRP gives these committees the power to approve, monitor, and disapprove research projects at an institution in accordance with this policy.

The IRB at Baylor University is composed of individuals with professional expertise, the researcher's peers and at least one non-Baylor member, in various areas of science, social science, ethics, law, medicine, statistics and research methodology.[1] Some academic units at the university have their own sub-committee to review the protocols before submitting to the IRB committee.

A protocol is the "plan for carrying out a scientific study or a patient's treatment regimen."[2] In this instance, the protocol is the document explaining the principal investigator's intentions to use human subjects in their research. As part of the research process, the principal investigator submits a protocol to the IRB committee for approval. The committee then determines if the use of the human subjects is justified, ethical and safe. At different stages of the research, the committee reexamines and monitors the use

of human subjects. Another role of the committee is to investigate complaints lodged by participants or patients of the research.

Computer-Supported Cooperative Work

"[A computer-supported cooperative work is] a generic term, which combines the understanding of the way people work in groups with the enabling technologies of computer networking, and associated hardware, software, services and techniques."[3] The development process studies the existing business culture and work process. A system designed to be compatible with the current social environment when possible. The process also takes the computer hardware and infrastructure into consideration. The goal of a computer-supported cooperative work is to facilitate collaboration amongst the people involved in the process.

Workflow Management System

A workflow management system is a CSCW that automates the work processes of all group members. A workflow management system is a software program that facilitates the management of a business process.[4] Part of the process in designing a system is to examine the work processes and how they function with each other. Another part of the process is to examine how the workers interact with the different work processes. The goal is to optimize the time and effort of the workers by automating the work processes. The Online Protocol Submission system automates the workflow process associated with a protocol for the IRB committee, starting at the creation of the form and ending at the committee decision.

Business Process Reengineering

Michael Hammer defines business process reengineering as "the fundamental rethinking and radical redesign of business processes to achieve dramatic improvements in critical, contemporary measures of performance, such as cost, quality, service, and speed."[5] The term's use is usually in conjunction with information technology and technological innovations. It is an approach used to introduce and maintain information technology in a business culture. The general process includes identify processes that need change, analyze current processes to determine how they need to change, design new technology driven processes to replace the current processes, and test and implement the new processes.

Social Engineering

The definition of social engineering has changed over the years. In information security and computers, it refers to the manipulation of an individual or a group to gain access to a computer system or to gain private information about a company or individual. This is not the definition referred to in this paper. An older definition of social engineering does not have a negative connotation. According to the Fontana Dictionary of Modern Thought, social engineering is "the planning of social change according to a blueprint, and the associated technology of social design and manufacture."[6]

Technological innovations have moved society into automating business processes. Automated business processes give some businesses a competitive advantage over others. Some business cultures have a lack of understanding of technology and its array of possibilities in facilitating business processes. Social engineering is an approach

used to help business cultures through the necessary social change to be ready to function with technology. Once a business culture understands and embraces the possible role of technology in their business process, the business process reengineering process leads a smooth transition.

CHAPTER THREE

Analysis

We met with the IRB committee members to discuss the necessary features of the protocol system. We discussed the following required features:

- Secure
- Portable
- Paperless
- User-Friendly

The users of the system are faculty, staff, and students of Baylor University. The system must have controlled permission levels and be secure. The permission levels are the Principal Investigator, Faculty Advisor, Department Chair, IRB Member, IRB Chair, and IRB Coordinator. Each permission level has different roles and duties in the system. The system has a main screen for each permission level where the user can view past, present, and pending protocols. Faculty or staff members may have multiple permission levels in the system. For instance, a faculty member can be a faculty advisor and an IRB member. A user would need access to multiple levels.

Faculty and staff at the university use a variety of different computer operating systems. The automated system must be able to run on any computer platform easily. The system is a web-based application written in PHP with a SQL database. Some pages utilize JavaScript functions. Any computer system is able to use the program with any web browser.

An objective of the project is to reduce the amount of paper used by the processes. Before each committee meeting, the IRB coordinator would make a copy of each

submitted protocol and distribute the copies to each committee member. This took time and effort. The automated system resolves this issue. The system reduces the time and effort necessary by storing the protocols in a database. Review and exchange of the protocols occurs in the virtual environment, eliminating the need for making copies and distributing them. A committee member is able to print a copy of a submitted protocol if desired.

The system is easy to learn and includes instructions at every step of the process. The design and workflow of the system follows the previous process. The system also gives confirmations when items are added, updated, deleted, and submitted.

The system also needs to be adaptable. The protocol procedure is not permanent. The government policy may change at any time. The university may decide to add or remove steps in the process. The system must be changeable without having to create a new automated system.

There are also multiple committees at the university with similar roles and responsibilities. The Office of the Vice Provost of Research saw the possibility of using the system for different committees. The system currently works for a particular committee, but should be easily adaptable for any committee that has a similar workflow process. Each step and permission level of the system is modular. If a module is not necessary for another committee, remove it from the system without breaking it. If a new module is necessary for another committee, add it to the system with little change to it. In turn, if the workflow process for the current committee changes, then you can add a new module with little effort.

Existing products researched do not satisfy the required features. They offered security, paperless process, and are user-friendly. Most of the products lack portability. All products researched lacked easy adaptability. The fields and data collected by existing products did not mesh with the current process at Baylor. Most over-the-counter solutions catered to the medical research facilities and not academic institutes. These products are not customizable to suit Baylor's needs without a substantial increase in cost.

One product researched is the popular program ProIRB.[7] This product is not portable since it is a system installed on a Window based machine. Customization was necessary and available at a considerable cost. With customization, the university would lose the ability to update the system with new releases or versions. The number of users determines the price of the product. To keep costs down, committee members and a person designated to input all IRB protocols would have access to the system. This would not remedy the time and effort issue. Overall, the system was not feasible for the purpose of the university.

It is not feasible to purchase an over-the-counter solution due to the cost of customization and the size of the university. Baylor chose to build a custom in-house system.

The Workflow Management System

The Online Protocol Submission system has the following processes:

- Profile editing
- Creating a protocol
- Editing an un-submitted protocol
- Submitting a protocol
- Faculty advisor signature
- Department chair signature
- Selecting IRB members to review protocol

- IRB member review
- IRB committee review
- IRB chair or committee decision
- Editing a resubmit protocol
- Resubmitting a protocol

Each user has a unique login account. The system uses Baylor's campus wide authentication system to grant access. The unique login also determines the different permission levels.

The first time you login, the user will edit their profile information. This information formulates the signature page and routing of the protocol. For instance, a student's protocol requires faculty advisor approval, determined by the profile information. The principal investigator saves the changes and moves to the virtual office screen as seen in Appendix A.1. This is the main screen for the entire system. The top navigation menu includes links to each system process. The bottom navigation menu includes links to create a new protocol and edit profile information.

The principal investigator creates a new protocol by clicking the "New Protocol" link. An IRB protocol has six sections:

- Signature Page
- Introduction
- Request for Expedite Review
- Methodology
- Informed Consent
- Instruments

The principal investigator completes all sections of the protocol. Each section saved individually. This gives the principal investigator the ability to complete the protocol in multiple sessions. The protocol main page shows each step of the protocol and its status, either new or saved. It also has a "Review Protocol" button to see how it will look to the faculty advisor, department chair, or IRB committee.

Once each section of the protocol is finished, a "Submit" button will appear at the bottom of the screen. The principal investigator clicks the "Submit" button to start the routing process. The principal investigator's portion of the automated system is complete. The system locks the protocol during the routing and approval processes. However, the principal investigator can track the progress on the protocol by using the virtual office.

The routing process completes the signature page. The system checks for completion of the six sections before routing it to the faculty advisor or the department chair, depending on the principal investigator's role. If the principal investigator is a student, the system sends an email to the faculty advisor for approval.

The faculty member logs into the system and clicks the "Faculty Advisor" link in the top navigation menu. This will open the faculty advisor screen as seen in Appendix A.2. The faculty advisor opens the protocol. A faculty advisor can approve or not approve a protocol, make comments about the proposed research, and choose whether a protocol is eligible for expedited review. Appendix A.3 is an example of this screen. To be eligible for expedited review, the proposed research must meet the following three criteria: the only involvement of research subjects is response to written, oral, or electronic surveys; the information requested in surveys does not include any highly personal or sensitive information; and the activity poses minimal physical and psychological risk to research participants. The faculty advisor saves the changes and returns back to the faculty advisor screen. The "Sign" button is now visible. The faculty advisor clicks the "Sign" button and the system routes the protocol to the department chair for approval by sending an email to the department chair for approval.

The department chair logs into the system and clicks the "Departmental Chair" link in the top navigation menu. This will open the departmental chair screen as seen in Appendix A.4. The departmental chair opens the protocol. A departmental chair can approve or not approve a protocol, make comments about the proposed research, and choose whether a protocol is eligible for expedited review. Appendix A.5 is an example of this screen. The departmental chair saves the changes and returns back to the departmental chair screen. The "Sign" button is now visible. The departmental chair clicks the "Sign" button and the system routes the protocol to the IRB committee for approval. The signature page is complete.

The system routes the protocol to the IRB chair screen, awaiting assignment of IRB members to review the protocol. Once the chair selects the reviewers, the system sends an email to each reviewer. The protocol moves from the "Protocols for Review Selection" table to the "Protocols Waiting for Reviewer Recommendation" table.

The member reviewer then logs into the system and clicks the "IRB Member" link in the top navigation menu. This will open the IRB member screen as seen in the Appendix A.6. The IRB member opens the protocol for review. There is a drop down menu with the possible recommendations. The IRB member can approve, approve with stipulations, send to full committee, or reject a protocol. Appendix A.7 is an example of this screen. If the other reviewer has already reviewed and submitted their recommendation, then the IRB member can see their recommendation and comments. There is also a field to save any comments about the protocol. The IRB member saves the changes and returns back to the IRB member screen.

The protocol moves to the "Protocols for Decision" table on the IRB chair screen once both reviewers make recommendations. The IRB chair decides on the next action. The IRB chair can decide to approve, approve with stipulations, send to full committee, table, not all stipulations met, and not approved.

If the IRB chair chooses to table or send the protocol to full committee then the protocol moves to the "Protocols for Committee Decision" table on each of the IRB member screens. T committee reviews the protocol at the next committee meeting. After the meeting, the IRB chair decides on the next action.

If the IRB chair approves a protocol with stipulations, then the system routes it back to the principal investigator for further explanation or changes. The system sends an email with details of the necessary changes. The principal investigator can then edit the protocol as necessary. Once the principal investigator makes all the changes, the principal investigator resubmits the protocol to the IRB committee.

If the IRB chair chooses not to approve a protocol, the system sends an email notifying the principal investigator of their denied protocol. The principal investigator can start the research.

If the IRB chair chooses to exempt or approve a protocol, the system sends an email notifying the principal investigator of this status. The principal investigator can start the research. This completes the Online Protocol Submission system process.

CHAPTER FOUR

Methodology

I used the following sources to gather evidence to examine the Online Protocol Submission system's ability to handle the increase in workflow of the IRB, the effectiveness of moving to an automated system, and the lessons learned from the experience:

- Existing Documentation
- Archival Records
- User Observations and Interviews

The first source is existing papers, studies, and documents on the definition of the process used to complete the project. I used these sources as references to understand the meaning and use of the terms described in the previous chapter.

The second source is archival records. The committee keeps records for 3 years. This restricted my access to data prior to the automated system. Notes from the development process gave some insight into the timeframe used in the manual process. This gives a premise for determining the effectiveness of the move to the automated system.

Data on the automated process comes from database queries from the submitted protocols. Calculations performed on this data show the timeframes between each step of the process. When compared to the manual process data, the effectiveness of the automated system is determined.

During the development process, we observed and interviewed key users. The key users included committee members and faculty members who submit a large number of protocols. This gives more background information on the manual process. We interviewed some of these key users after the launch of the automated system, exploring their experience with the transition from the manual to the automated system.

CHAPTER FIVE

Results

A successful business process reengineering project benefits the business and improves the business process in some fashion. The Online Protocol Submission system at Baylor University was a success. It reduced the processing time of a protocol from beginning to end. Even with an influx of protocols due to an increase effort of research at Baylor, the system takes less time than the manual process.

Research

At the start of the development project, I was not following any set guidelines or best business practices. Over there years, I learned a programming process that worked for my colleagues and me. I discovered from researching existing documentation that I was following an accepted best business practice for business process reengineering in order to change a workflow management using computer-supported cooperative work. This project was tougher than previous projects because the business culture was not ready for the necessary change. It was necessary to work hard to get the users of the system to understand the culture that surrounds a workflow management system.

Fist, they did not understand the scope of the project. The idea was to automate some of the current processes in order to better support the mission of Baylor. Some involved with the project felt that we could change the current process drastically since we were changing one aspect. I explained to them that this was not feasible. The users will not like the automation change to the process. Completely changing the process and

then automating it will set the project up for failure. Instead, the scope of the project was leave the business process the same, changing only the means in which one would submit a protocol.

Initially, my job was to come in and identify the processes easily automated with the modern technology of the time. Some steps were not possible with the modern technology or easily accomplished with the modern technology. One step is to place a watermark or IRB seal on the consent form so that there is no discrepancy as to which is the approved consent form. We determined to leave this step of the process as a manual process. Any electronic watermark procedure we put in place at the time could easily be re-fabricated, leading to a lack of assurance present with the current manual process.

Second, I reviewed and analyzed the current processes for redundancy and unnecessary steps. Michael Hammer states that the major challenge for managers is to obliterate non-value adding work, rather than using technology for automating it.[8] That was a challenge for me. I was on a project where I was certain which processes were necessary and unnecessary. Of course, most involved in the project thought the entire process was necessary. For instance, a user signs a form by logging into an automated system, using the system, and saving information in the system. The database tables have a timestamp and a user field to track changes to an entry. The committee members would not accept this as an electronic signature. Instead, we added an additional step with a "Sign" button in order to resemble the act of signing and submitting each step. It does not slow the process down, but some users miss that extra step, holding up some protocols from continuing down the workflow process. The results section explores this further.

According to an FBI article published in August 2005 that depicts their initiative towards automating their process, Figure 1 shows that I am following the Business Process Reengineering Cycle. The remaining steps of the cycle are to "design to-be" and "test and implement to-be."[9]

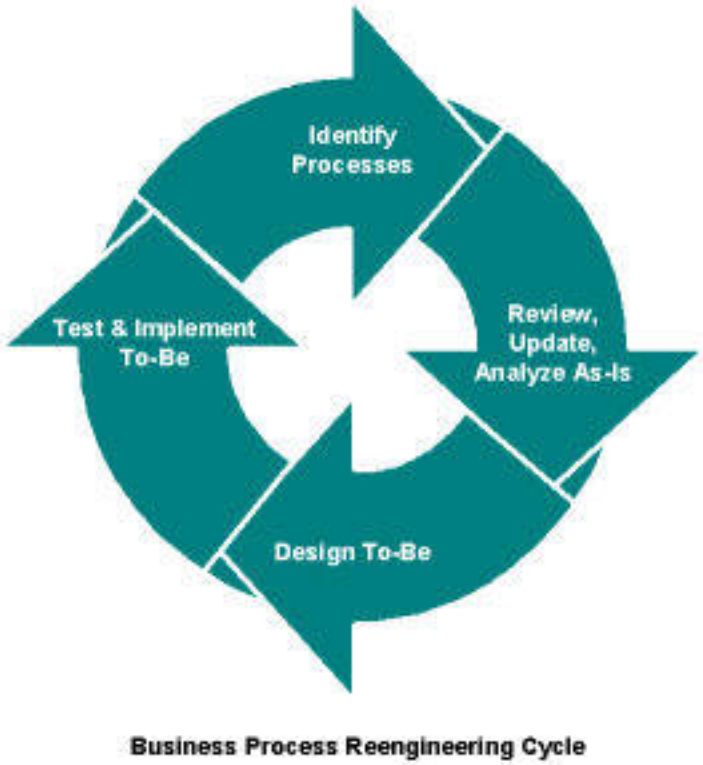

Figure 1. Business Process Reengineering. Copied from the Federal Bureau of Investigation

As part of the design process, I observed some of the committee members during the manual process and asked them questions regarding the procedure. The consensus is that the committee tried to complete protocols within a one-week window, but reached a two week turn around window most of the time. Part of the problem of the manual process is the use of campus mail to deliver everything. Principal investigators sent protocols to each signee usually by way of campus mail. When the signature page is complete, the principal investigator sends the protocol through campus mail to the IRB

chair. The IRB coordinator sends two copies of the protocol through campus mail to the reviewers. The reviewers send the copies back with comments and recommendation. If necessary, the IRB coordinator sends a copy of the protocol to each member of the committee prior to the committee meeting. Finally, the IRB coordinator sends a letter to the principal investigator explaining the decision of the IRB chair or committee. It is evident that the involved parties waste a lot of time waiting for items in the mail in order to complete the different steps.

Unfortunately, the principal investigator cannot start the research until the entire process is complete. In extreme circumstances where the committee did not understand the research, the protocol could go back and forth between the principal investigator and IRB committee, prolonging the process time to 6 weeks or more. This will be the premise for determining the effectiveness of the move to the automated system. To be successful, the system should reduce the processing time in general to less than two weeks, preferably less than a week.

Database Queries

The automated protocols are the key to determining the new processing time. As stated earlier, the system records a timestamp and a user identity field with each database change. We can use this field to measure the start and end of each step of the process. The main processes in review are the submission, signature, resubmission, and overall approval processes of a protocol. These are the significant steps to processing a protocol. If the processing times are not less than two weeks and closer to a week, then the automated system is not improving the business process in question. We will look at each of the academic calendar years that the automated system has been online, starting

with 2005 – 2006 and ending with 2008 – 2009, the current calendar year. The academic calendar year starts in August and continues to July of the following year. Appendix B shows general statistics of the system for each of the academic calendar years.

Each of the following tables is set up with the same parameters for better comparison. The number of days is not uniform for a visual effect. We use the first categories, less than a day and 1 to 3 days, to reflect better the actual processing time instead of using one category for less than a week. The next couple of categories are used as are projected processing times. Items within the first four categories show that the processing time of the automated system is as good as or better than the manual process. The fifth category is in another week separation to show those items that missed the acceptable processing time. The final five categories are month separations.

Protocol Submission Time

The submission process is not comparable to the manual process. It is not possible to determine the submission processing time without surveying the principal investigator. The processing time will vary depending on the principal investigator and urgency of approval. However, it is important because it gives a glimpse into the expectation of the users. A user will expect that the committee would match the time and effort they put forth. If it does not take the principal investigator long to create a protocol, then it should not take long for the committee to decide on the protocol.

The submission processing time is the time between the start time of the protocol and time the principal investigator submits the protocol for signatures. We calculate this by subtracting the timestamp of the Protocol creation entry from the timestamp of the principal investigator submitted entry. The processing time of each calendar year is show

in Table 1. Less than 15% of the protocols each year take more than two weeks to submit. Therefore, 85% or more protocols each year are within the projected range of less than two weeks and closer to a week. As can be seen, the target processing time is accurate.

Table 1. The Submission Process Times

Days	2005 -- 2006	2006 -- 2007	2007 -- 2008	2008 -- 2009	Total
< 1	102	105	126	109	442
1 to 3	15	11	15	13	54
3 to 7	18	11	9	7	45
7 to 14	7	8	6	7	28
14 to 21	14	4	3	4	14
21 to 30	1	4	6	1	12
30 to 60	7	2	2	4	15
60 to 90	2	3	0	1	6
90 to 120	1	0	0	0	1
> 120	2	4	3	0	9
Total:	169	152	170	146	626

In the existing academic calendar years, the principal investigator submits about 60% of the protocols for signature in less than a day. This could be a concern, considering that this data gives us glimpse into the expectation of the principal investigator. However, this data does not take into account the amount of time spent prior to using the automated system getting the information ready. Most protocols coincide with a grant protocol or research project. As appendix C shows, the Protocol Form requests general information also requested on any grant protocol or research project description.

Protocol Signature Time

The signature process is present in the manual and the automated processes. In both, the step happens before reaching the IRB committee. It is an important step to streamline even though it is not a direct IRB committee step. This step does not reflect

on the automated system's performance to any high degree. This step is a way to transition the users into an automated system. It gives the principal investigator an idea of what to expect from the automated system. In addition, it provides a way of getting the protocol into the system with no effort from the IRB committee and gives the principal investigator a way to check on the status of the protocol.

There are three separate signature-processing times to study. The first processing time is the time it takes a faculty advisor to sign a protocol after submission by a student. The second processing time is the time it takes for a department chair to sign a protocol after a faculty advisor has signed it. The final signature process time is the overall processing time it takes a department chair to sign a protocol after a principal investigator, both students and faculty, submits it.

Table 2 depicts the signature processing times for a faculty advisor. We calculate this by subtracting the timestamp of the principal investigator submission entry from the timestamp of the faculty advisor submission entry. As seen on the table, close to 90% of the protocols each year are within the target processing time.

Table 2. The Signature Processing Times for a Faculty Advisor

Days	2005 -- 2006	2006 -- 2007	2007 -- 2008	2008 -- 2009	Total
< 1	49	43	67	44	202
1 to 3	13	3	6	8	30
3 to 7	5	6	7	12	30
7 to 14	11	6	2	11	30
14 to 21	0	2	1	3	14
21 to 30	3	3	2	1	9
30 to 60	1	2	2	3	8
60 to 90	2	1	2	1	6
90 to 120	0	0	1	0	1
> 120	0	0	0	0	0
Total	84	66	90	83	330

Faculty advisors sign off on the protocols in a suitable amount of time. Again, the table shows that faculty advisors sign about 60% of the protocols in less than a day. Faculty advisors are usually part of the protocol writing process and see many drafts of the protocol before inputted into the automated system. When it comes time for them to sign, they have already read the protocol and recommended the necessary changes in order for them to sign. The signature process is still a step before the protocol gets to the IRB committee.

Table 3 depicts the signature processing times for a department chair after faculty advisor signature. We calculate this by subtracting the timestamp of the faculty advisor submission entry from the timestamp of the department chair submission entry. More than 80% of the protocols the first year and over 95% of the protocols in the other years are within the target processing time.

Table 3. The Signature Processing Times
For a Faculty Advisor to a Department Chair

Days	2005 -- 2006	2006 -- 2007	2007 -- 2008	2008 -- 2009	Total
< 1	50	50	65	76	241
1 to 3	4	3	17	3	27
3 to 7	11	4	6	1	22
7 to 14	5	4	1	0	10
14 to 21	4	1	0	1	6
21 to 30	4	0	0	0	4
30 to 60	3	1	1	0	5
60 to 90	0	0	0	0	0
90 to 120	0	0	0	0	0
> 120	3	0	0	0	3
Total:	84	63	90	81	318

Table 4 depicts the overall signature processing times for every protocol. We calculate this by subtracting the timestamp of the principal investigator submission entry from the timestamp of the department chair submission entry. The trend from the first

three tables continues. The data shows that 75% or more protocols each year are within the target processing time.

Table 4. The Overall Signature Processing Times

Days	2005 -- 2006	2006 -- 2007	2007 -- 2008	2008 -- 2009	Total
< 1	66	86	100	73	325
1 to 3	18	10	23	21	72
3 to 7	14	19	26	16	75
7 to 14	14	10	5	16	45
14 to 21	13	8	1	4	27
21 to 30	14	6	4	1	25
30 to 60	4	4	3	6	17
60 to 90	2	1	2	1	6
90 to 120	0	0	0	0	1
> 120	5	1	1	0	6
Total:	150	145	165	138	599

This is the first time we see protocols take over 120 days to process. The hold up on these protocols stems from issue discussed earlier about the "Sign" button. The faculty advisor, department chair, or both make their selection in a timely manner, but forget to click the "Sign" button. Therefore, the protocol sits until someone moves it along the automated process. This occurrence happens less than 3% of the time. We include these outliers in the future tables, but we give them no further attention.

Protocol Resubmission Times

The resubmission process is not a step that every protocol must complete. Protocols that need further explanation or minor changes for approval go through this step. In the manual process, this step could significantly slow down the overall approval process. It is important to review this process to see if the automated system has also sped up this part of the process. It is a decision category, but it is not a terminating category. The system continues to route the protocol.

There are two processing times to discuss. First, there is the processing time of the principal investigator to make changes to the protocol and resubmit the protocol for another review. Second, there is the processing time of the review process after the protocol's resubmission. The IRB committee requests further explanation or changes to about 25% of the protocols each year. It is not a significant number, but it does effect our overall approval processing time.

Table 5 depicts the time it takes a principal investigator to make changes to the protocol and resubmit it. This is calculated by subtracting the timestamp of the approved with stipulations entry from the timestamp of the principal investigator resubmission entry. Principal investigators resubmit over 75% of the protocols within the target processing time. There are not many outliers in this table. I attribute this to the principal investigator being anxious to start the research.

Table 5. The Resubmission Processing Time

Days	2005 -- 2006	2006 -- 2007	2007 -- 2008	2008 -- 2009	Total
< 1	15	15	12	6	48
1 to 3	6	5	8	7	26
3 to 7	7	16	20	4	47
7 to 14	3	4	6	4	17
14 to 21	2	2	0	2	6
21 to 30	3	1	0	2	6
30 to 60	3	2	2	2	9
60 to 90	1	1	0	0	2
90 to 120	0	1	2	0	3
> 120	0	0	0	0	0
Total:	40	47	50	27	164

This is first time that most of the protocols are not in the less than a day category. However, principal investigators resubmit the majority of the protocols within a week. Unlike the beginning of the automated process, the principal investigator does not always have the requested clarification readily available.

This table also includes some special cases. The special cases are the protocols for resubmission multiple times. After resubmission, the IRB committee needed further explanation. These special cases make up less than 3% of the total number of protocols asked for resubmission.

Protocol Approval Time

The overall approval process is important because it gives us a general picture of the automated process. Most reflection of the manual process deals with the overall processing time. Since the preceding steps are faster than the manual process, the overall approval processing time should be faster.

There are the terminating categories that the IRB committee can decide. A protocol can be exempt, approved, or not approved. After each of the approval processes, the automated system is complete. The system does not route the protocol through any other steps.

Separate tables depict each terminating category. We calculate these by subtracting the timestamp of the principal investigator submitted entry from the timestamp of the IRB committee decision entry. The difference in the three terminating categories stems from the number of steps needed to arrive at each of the categories.

The different portions of the approval process are review selection, member review, committee review, and decision. When a protocol arrives at the IRB committee, the IRB chair selects two reviewers or decides that reviewers are not necessary. The committee members selected to review the protocol make comments and a recommendation. If the reviewers recommend sending the protocol to the full committee for review, then the committee reviews the protocol the next committee meeting. After

member review or after full committee review, the IRB chair decides the next action and the system sends an email to the principal investigator.

Exempt protocols typically go through the signature and an expedited approval processes which means they do not go through the member review or committee review portions of the approval process. Table 6 depicts the time it takes a protocol to go from being submitted by the principal investigator and being exempt by the IRB committee. Of all the exempt protocols, 50% of the first two years, 70% of the third year, and 90% of the current year were within the target processing time.

Table 6. The Overall Exempt Processing Times

Days	2005 -- 2006	2006 -- 2007	2007 -- 2008	2008 -- 2009	Total
< 1	4	3	11	14	32
1 to 3	4	2	7	12	25
3 to 7	11	9	7	16	43
7 to 14	8	2	4	5	19
14 to 21	7	7	2	1	17
21 to 30	3	2	2	1	8
30 to 60	4	4	5	3	16
60 to 90	2	2	2	0	6
90 to 120	0	0	1	0	1
> 120	5	0	1	0	6
Total:	48	31	42	52	173

The member review and committee review portions are very time consuming. The member review is as fast as the reviewer can make time to review and submit the recommendation. The committee review takes time because committee meetings are only once a month and less often in the summer session. The table also shows that small percentages, approximately 30%, of the protocols are exempt.

The majority, approximately 60%, of the protocols are approved. Approved protocols typically go through the signature and approval processes. Some approved protocols go through the resubmission process while others do not go through the

committee portion of the approval process. Table 7 depicts the time it takes the principal investigator to submit a protocol and it takes the IRB committee to approve a protocol. The table shows that very few protocols complete the entire process in less than a day. Almost 60% of the approved protocols each year take longer than two weeks and less than two months.

Table 7. The Overall Approval Processing Times

Days	2005 -- 2006	2006 -- 2007	2007 -- 2008	2008 -- 2009	Total
< 1	1	3	0	1	5
1 to 3	0	0	4	0	4
3 to 7	10	3	7	9	29
7 to 14	14	22	19	25	80
14 to 21	13	14	13	12	52
21 to 30	12	14	12	9	47
30 to 60	23	16	28	14	81
60 to 90	0	2	4	4	10
90 to 120	1	1	2	0	4
> 120	0	4	1	0	5
Total:	74	79	90	74	317

These numbers do not reflect actual time spent only in the approval process. We calculate this by subtracting the timestamp of the department chair submitted entry from the timestamp of the IRB committee decision entry. The decision entries include exempt, approved, and not approved. Table 8 depicts the actual approval process times. This is the amount of time a protocol with a decision takes to go through the different portions of the approval process. For the first three years, close to 50% of the protocol were within the target processing time. About 25% of the protocols were between the 2 to 4 weeks timeframe. Considering that about 25% of the protocols require further explanation as stated above, these numbers support our argument. The chance that this set of protocols received an initial decision within two weeks is high.

Table 8. The Approval Processing Times

Days	2005 -- 2006	2006 -- 2007	2007 -- 2008	2008 -- 2009	Total
< 1	17	5	12	35	69
1 to 3	3	3	9	14	29
3 to 7	17	7	15	19	58
7 to 14	16	22	23	29	90
14 to 21	13	16	14	11	54
21 to 30	14	7	12	6	39
30 to 60	7	13	30	12	62
60 to 90	2	2	5	1	10
90 to 120	1	1	2	0	4
> 120	4	2	2	0	8
Total:	94	78	124	127	423

The current year reflects the anticipated data the most. 76% of the protocols fall within the two-week mark. Looking at the trend of numbers from year to year, we see that protocols are falling closer to the anticipated target with every year. This is true for any workflow management project. There must be a reasonable amount of time to achieve the anticipated results. Business process reengineering projects do not produce results immediately.

The final terminating decision is not approved. Not approved protocols typically go through the signature, the complete approval and resubmission processes. These protocols go to full committee. Very few are not approved without the chance to make revisions. Table 9 depicts the time the principal investigator takes to submit a protocol and the IRB committee not to approve the protocol. This is the lowest terminating category with less than 2% of all submitted protocols are not approved. The table shows that there were zero not approved protocols in the first year. The second year had the most with five not approved protocols. The third and fourth year had only one not approved protocol each. The table also shows that most not approved protocols take more than the target processing time. This is acceptable, since the processing time argument is a moot point.

Table 9. The Overall Not Approved Processing Times

Days	2005 -- 2006	2006 -- 2007	2007 -- 2008	2008 -- 2009	Total
< 1	0	1	0	0	1
1 to 3	0	0	0	0	0
3 to 7	0	1	0	0	1
7 to 14	0	1	0	0	1
14 to 21	0	0	1	1	2
21 to 30	0	1	0	0	1
30 to 60	0	1	0	0	1
60 to 90	0	0	0	0	0
90 to 120	0	0	0	0	0
> 120	0	0	0	0	0
Total:	0	5	1	1	7

The principal investigator gets a chance to correct the protocol in order to be approved. The IRB committee is not in the practice of turning down potential research at Baylor. Only protocols that cannot overcome an ethical issue by corrections are directly not approved.

Key User Interviews

There were 10 key users chosen from the processes. These users used both the manual and automated process. Most of the users had multiple roles in the system such as faculty advisor, department chair, IRB member, or IRB chair.

The facial expressions of these individuals at the start of the interview were most interesting. Most key users had relinquished one or more of their roles in the system by interview time. A look of horror came across their face and quickly turned to a look of disgust that I would even mention the IRB to them. However disgusted at the thought of the IRB, each key user chose to answer the questions.

When asked about their experience with the manual protocol submission process, most users described it as cumbersome, time consuming, and too much paperwork. Their role in the IRB was not their primary task at the university. They completed their regular

workload along with the time consuming work of the IRB. Each of the interviewees stated that the new program made their job so much easier.

I asked the interviewees which process, in their opinion, took the most time to complete. All interviewees stated that the manual process took much longer than the current system. The automated system breaks out each component of the process into its own entity. This gives the feeling that the user is interacting with a couple of different smaller system instead of one long and drawn out process.

Most of the interviewees, about 80% were happy with their experience with the automated protocol submission process. They stated that there was not much of a learning curve in the transition from the manual to automated process. The layout of the automated system makes the workflow much smoother. Instructions are not necessary in order to understand the next step. However, each step lets you know the basic process of completing the task.

Not one key user mentioned the online help guides present on the IRB website with further detailed instructions on how to use each of the components of the automated process. Most did not even know they exist when questioned about them. One of the issues with changing the culture at Baylor has been the online help guides. The online help would clear up the majority of questions asked through technical support.

Finally, I asked what portions of the automated process they would change. Half of the interviewees mentioned the signature step. Most of them have become victim to the "Sign" button by either forgetting to click it themselves or by having their protocol held up from not clicking the button. Some users would like to add a version of the system for their internal department process. Other users cannot wait for university to

automate other workflows such as the Curriculum Action Form. This is another form where a large portion of the processing time is spent waiting for routing of the form through campus mail.

Overall, the experience of each user with the transition from the manual to the automated process was pleasant. Two key users mentioned the system being online as a key to its success. Both interviewees told a story of how one member of the process was not available on campus due to one reason or another, but their protocol was not help up because they did not have to wait for that individual to get back on campus. Instead, the individual viewed it from there present location and signed the protocol, moving along the process. This is not easily achieved and as quickly with the manual process. Similar stories from other users not interviewed have emerged over the years.

CHAPTER SIX

Conclusion

The automated system is effective in handling the influx of protocols. The system reduced the processing time for more than half of the protocols in each of the different processes tested. In many cases, the system reduces the processing time to less than a day. The IRB committee is able to process more protocols in less time.

The workflow management system helped improve the business process. It streamlined certain aspects of the process, making the process quicker. The Online Protocol Submission system ran into some opposition, but overcome it immediately. It reduced the processing time of a protocol from beginning to end.

The business process reengineering cycle is continuous. The process never ends. This paper is part of the process. We can use this paper in an effort to review and analyze the current automated processes for redundancy and unnecessary steps. We should alter or remove some process in place.

Limitations

A major limitation of this paper is the lack of data from the manual process. The superficial research done during the project helped to set a basis for work. However, the actual numbers may have revealed that the processing times from start to finish for the manual process are closer to 4 weeks for the majority of protocols.

Another limitation is the lack of interview questions and no survey of all the users in the automated system.

Further Exploration

One aspect not discussed in this paper is research on the number of research projects on campus that should submit an IRB protocol for approval, but do not. It would be difficult to gather information on this topic. Faculty, staff and students at most universities would not think that they were doing research on human subjects that warrants IRB approval. Some know they should submit protocols and do not. They will not confess to avoid punishment. However, it would be interesting to see such data from any university.

Another aspect that warrants further exploration is the ongoing effect of the Online Protocol Submission system on the university community and culture. After the successful launch and use of this system, the university began the process of automating a variety of internal staff and faculty procedures. One example is the Curriculum Action Form, which currently has a task force working on the business process reengineering cycle.

Endnotes

[1] "The Role and Membership." The Baylor University Institutional Review Board Website. http://www.baylor.edu/research/irb/index.php?id=20752.

[2] The Definition of a Protocol. The Dictionary.Com website. http://dictionary.reference.com/browse/protocol.

[3] R.W. Root. "Design of a multi-media vehicle for social browsing". *Proceedings of the 1988 ACM conference on Computer-supported cooperative work*, pp. 25-38.

[4] T. Gross and S. Pekkola. "Analysing a Workflow Management System: Three Levels of Failure". *CHiMiT '08: Proceedings of the 2nd ACM Symposium on Computer Human Interaction for Management of Information Technology*.

[5] M. Hammer and J. Champy. *Reengineering the Corporation: A Manifesto for Business Revolution*. p. 32.

[6] A. Bullock. *The Fontana Dictionary of Modern Thought*. p. 784.

[7] ProIRB for the IRB Professional. ProIRB Plus Inc. http://www.proirb.com/

[8] M. Hammer. "Reengineering Work: Don't automate, obliterate." *Harvard Business Review* (Jul/Aug 1990): pp. 106.

[9] Business Process Reengineering (BPR) initative update. The Federal Bureau of Investigation. http://www.fbi.gov/hq/ocio/articles/bpr.htm

APPENDICES

Appendix A

Screen Shots

Figure A.1. Virtual Office Screen

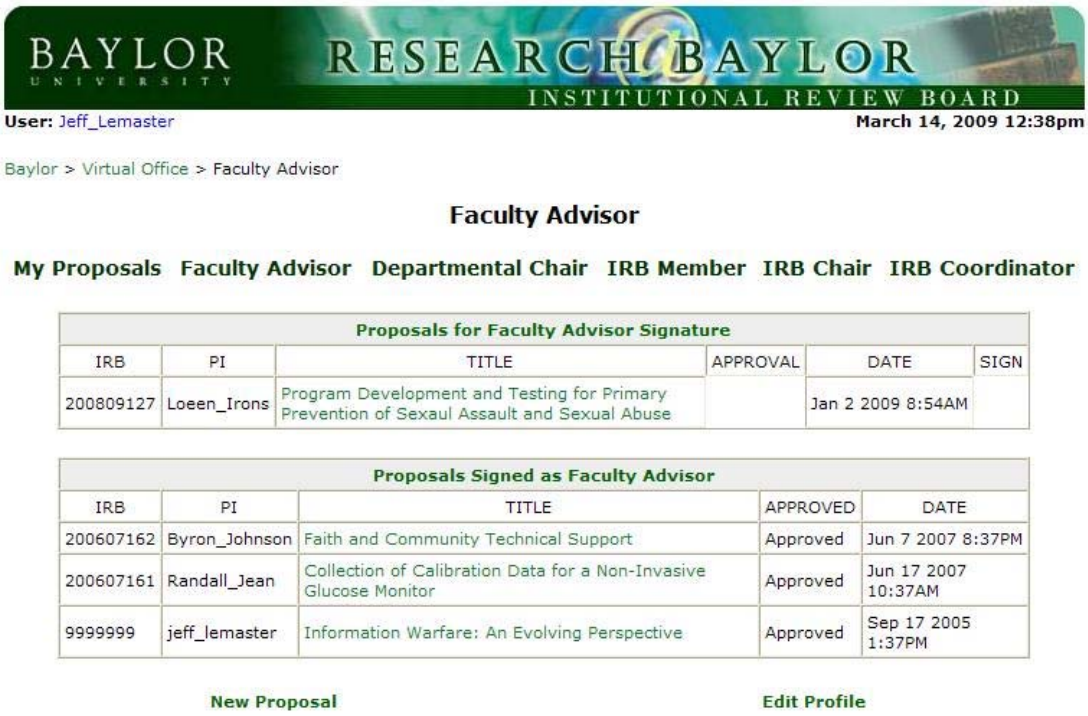

Figure A.2. Faculty Advisor Screen

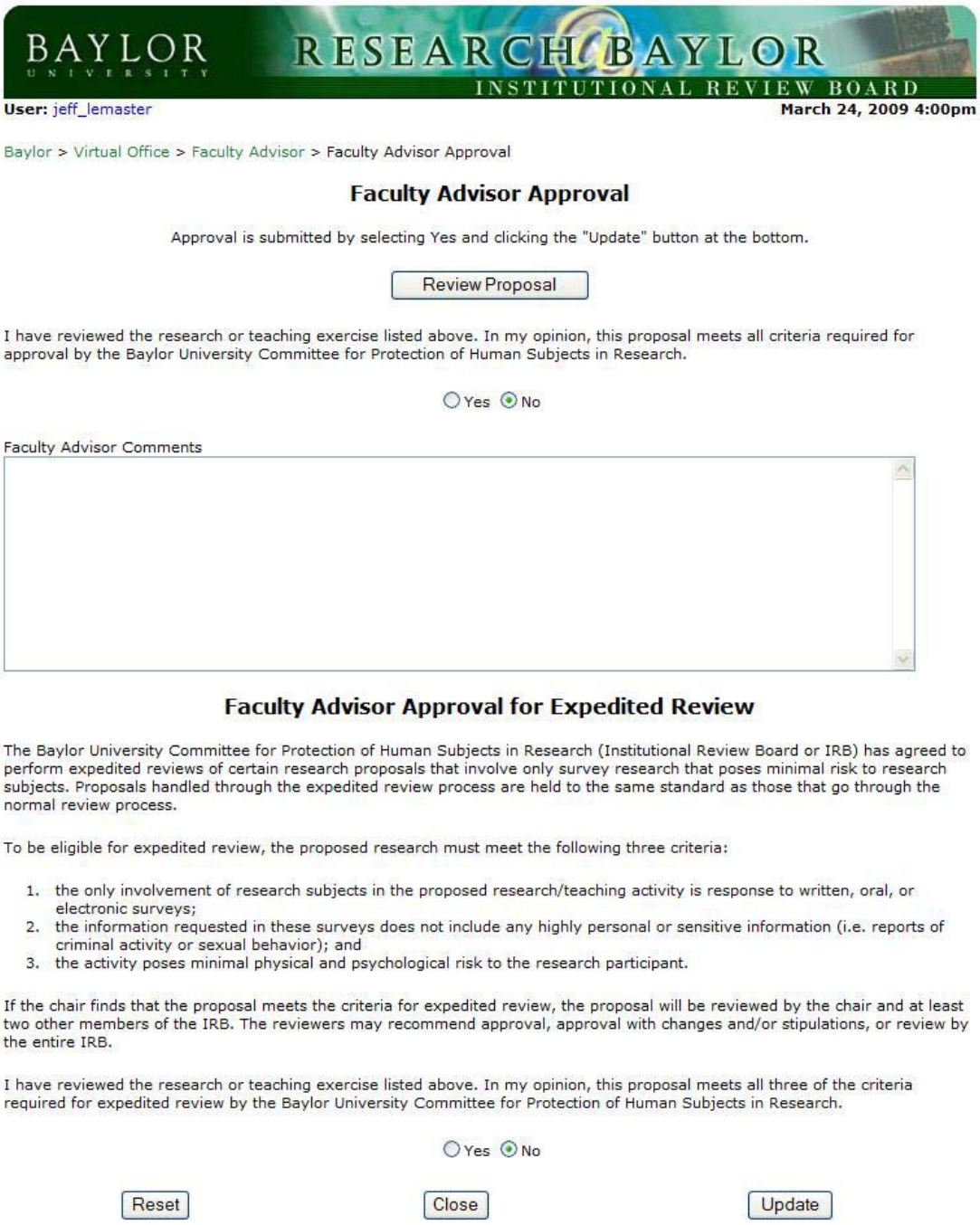

Figure A.3. Faculty Advisor Approval Screen

Figure A.4. Departmental Chair Screen

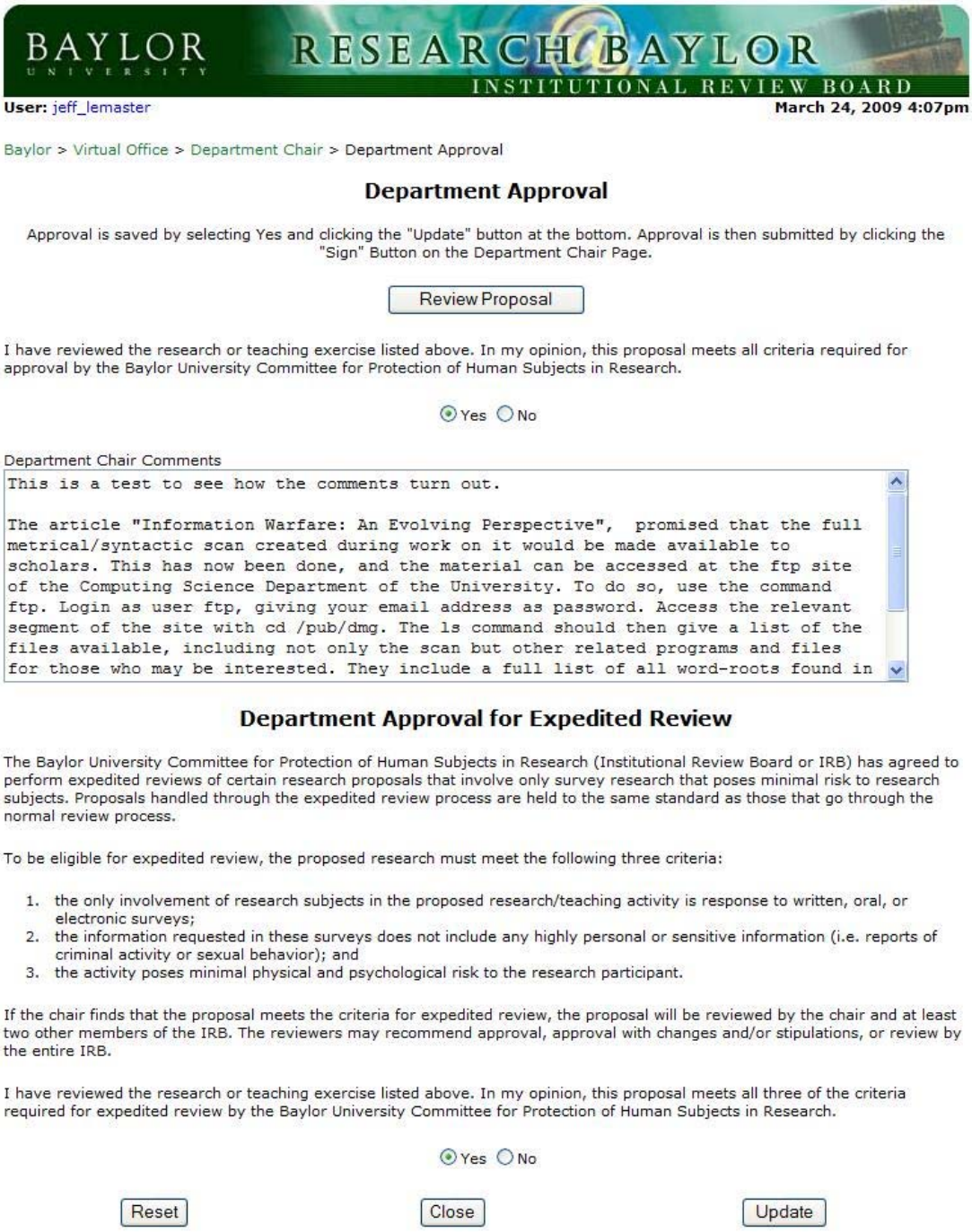

Figure A.5. Departmental Chair Approval Screen

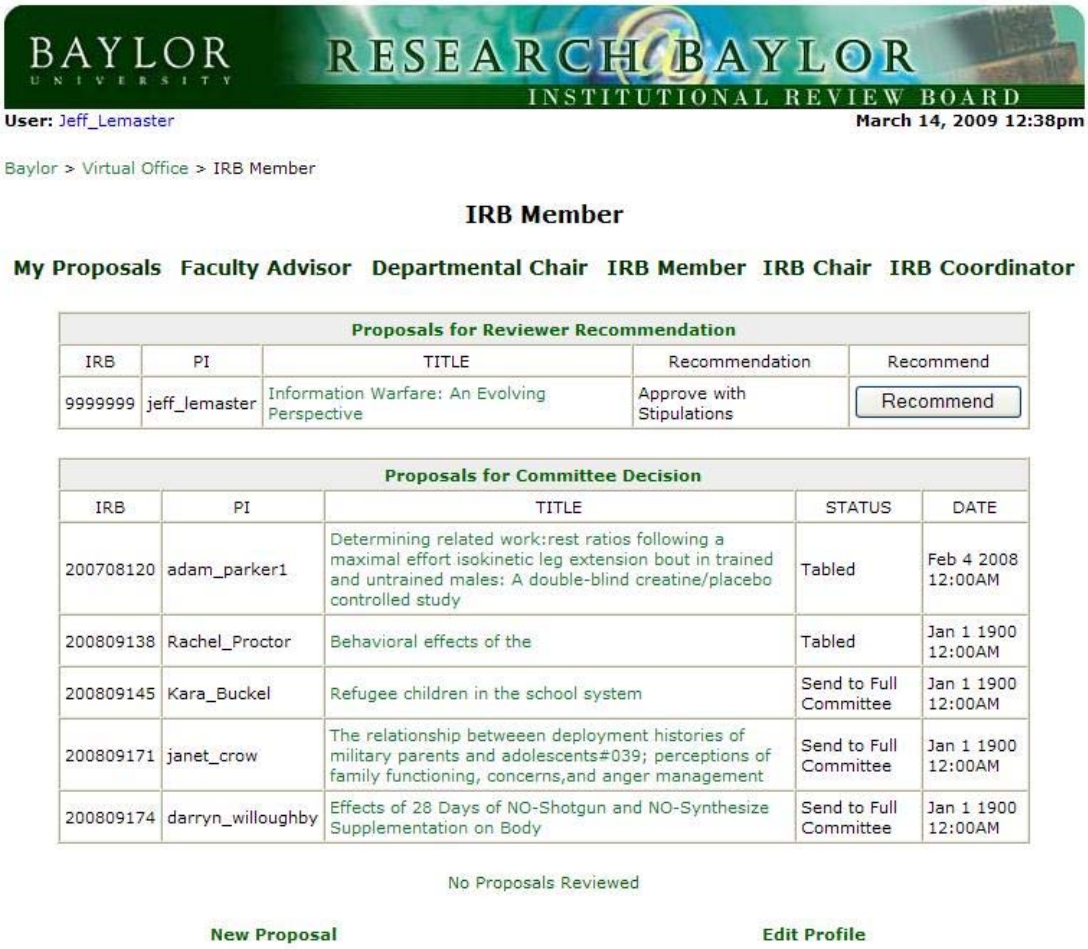

Figure A.6. IRB Member Screen

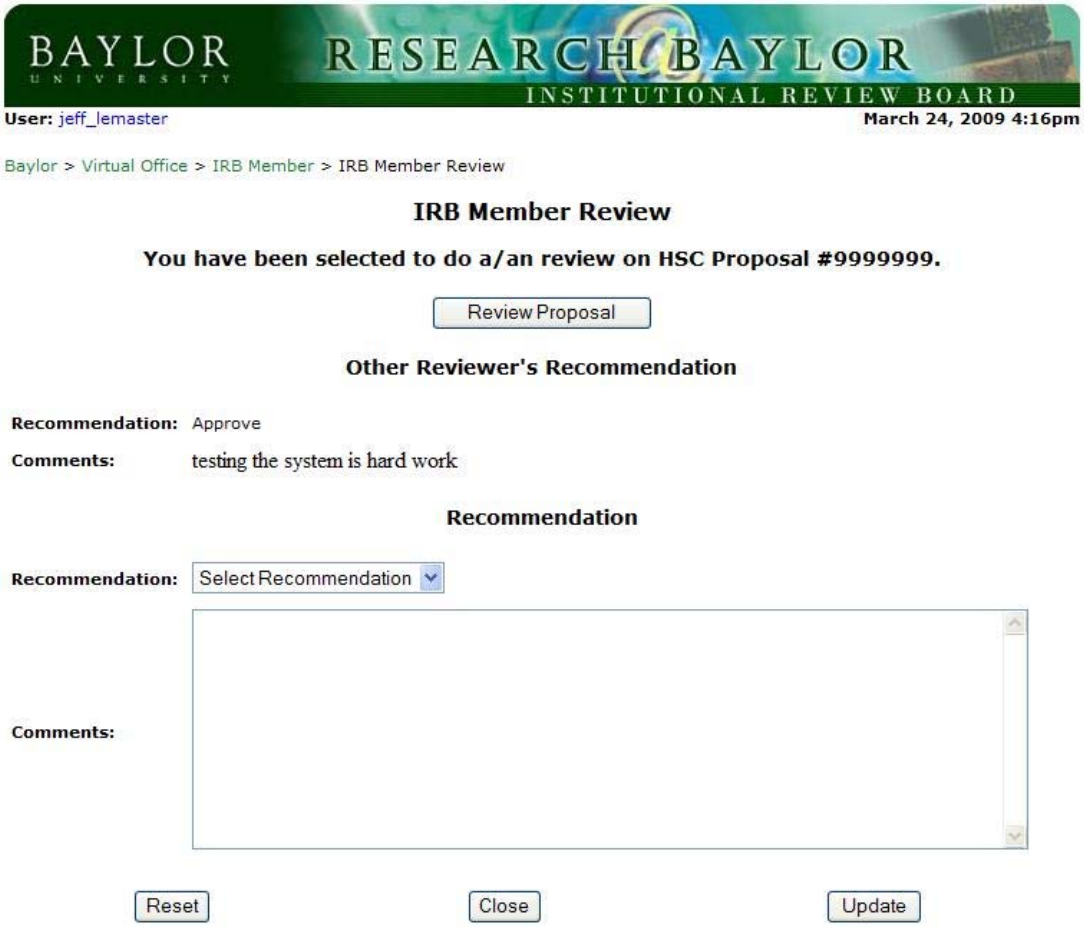

Figure A.7. IRB Member Review Screen

Appendix B

General Statistics Tables

Table B.1. Submission Totals by Academic Calendar Year

Years	Principal Investigator:			Signatures:	
	Started	Submitted	Resubmitted	Faculty Advisor	Department Chair
2005 - 2006	178	166	47	89	158
2006 - 2007	167	160	50	68	149
2007 - 2008	186	179	50	92	175
2008 - 2009	170	150	30	85	141
Totals:	701	655	177	334	623

Table B.2. Decision Totals by Academic Calendar Year

Years	Approved	Resubmit	Not Approved	Tabled	Exempt
2005 - 2006	83	58	1	0	67
2006 - 2007	98	53	3	0	53
2007 - 2008	108	58	4	1	58
2008 - 2009	83	36	1	1	52
Totals:	372	205	9	2	230

Table B.3. User Totals by Affiliation

Affiliation	Total No.
Students	311
Faculty	308
Outsiders	2
NULL	27
Profile Users	735

Table B.4. User Role Totals

Role	Total No.
IRB Members	24
Department Chair	102
Departments	84
Dean	6

Appendix C: Protocol Form

Baylor University
Committee for Protection of Human Subjects in Research

The Baylor University Committee for Protection of Human Subjects in Research is the official university Institutional Review Board (IRB) for the protection of human subjects or participants in laboratory learning experiences at or connected with Baylor University.

Baylor IRB Role and Membership

The role of the committee, broadly defined, is to ensure the safety of humans involved in research laboratory activities conducted by Baylor University, its employees, or agents. Whereas the IRB believes it is charged with facilitating and enabling responsible use of humans in pursuit of our academic goals, it also feels that the central role of the IRB is to ensure the ethical and safe use of human subjects who are fully informed as to their role, the risks attendant to their participation, and their rights as participants.

The IRB is composed of people with professional expertise in various areas of science, social science, ethics, law, medicine, statistics, and research methodology. In addition, the committee always has at least one member chosen from the Waco community who has no formal ties with Baylor University. A list of current IRB members can be obtained from: Dr. Matthew S. Stanford, Chair, Baylor University IRB, Department of Psychology and Neuroscience, One Bear Place #97334, Waco, TX 76798-7334, 254-710-2236 tel, 254-710-6759 fax.

Activities Requiring IRB Approval at Baylor University

The Baylor IRB must approve of activities that fall into any of the following categories:

1. Research projects involving the use of humans as subjects:
   a. whether the procedure involves no risk or considerable risk;
   b. whether or not the protocol involves deception of subjects;
   c. if the subjects are Baylor students (regardless of the identity of the investigators);
   d. if the investigators are Baylor employees (regardless of the source of subjects).
2. Classroom or laboratory activities, except in clinical therapy training in the professional health care field, involving any of the following:
   a. physically invasive activities such as blood drawing;
   b. physically taxing activities such as a stress test;
   c. physiological recording such as EKG or EEG;

d. any activity where the student must ingest any substance (other than food);
e. any psychological or personality testing or any testing procedure not aimed at academic evaluation;
f. any activity where there is a risk of personal information becoming public;
g. any painful procedure;
h. any procedure involving psychological risk;
i. any activity where the student is or might be exposed to risk of contact with any
potentially dangerous, infectious, toxic, or radioactive substances.

Research activities in which the only involvement of adult human subjects will be in one of the following categories are exempt from IRB review;

1. Anonymous surveys or questionnaires
2. Research involving the study of existing data, documents or records if these sources are publicly available or if the information is recorded in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

These exemptions do not include studies involving minors as participants or archival data previously gathered from minors. The Baylor IRB chair, in consultation with the IRB as deemed necessary, retains final judgment as to whether a particular activity is covered by this policy. Investigators who believe their study is exempt from review must submit a completed proposal to the IRB chairman to receive an exemption waiver.

If you have a question about whether these guidelines apply to a particular protocol you are interested in implementing, or of which you are aware that is currently being implemented at Baylor University or using Baylor students as subjects, you are encouraged to contact Dr. Matthew S. Stanford, 254-710-2236.

Criteria for Proposal Approval by the Baylor IRB

The following criteria is used by the Baylor IRB to evaluate protocols:

1. The clarity of exposition as it influences the committee's ability to understand the background, aim(s), scope, procedure(s) and experimental method(s) of the protocol.
2. The nature and proposed implementation of the safeguards the author(s) proposes to limit the possibility of injury, loss of confidentiality, or embarrassment to participants.
3. The structure and content of the "Informed Consent Form" to ensure that the form fully, comprehensively, and lucidly explains the aims and procedures of the experiment as well as the options, benefits, safeguards, and remedies, if any, afforded the participants.
4. In assessing the balance of benefit and risk, the committee may consider:

a. The scientific merit of the protocol, i.e. whether the outcome represents a potential contribution to the scientific knowledge base; and/or
b. The pedagogical aim(s) of the protocol, i.e. whether or not it represents a valuable learning experience for a student investigator or for students involved in classroom or laboratory experiences.

Departmental Review

The committee feels that in most cases scientific merit is best judged by peers. Towards this end, the committee requires the signature of the chairperson of the protocol author's academic or administrative department (or the Chair's designate) indicating that the chair has reviewed the proposal and to the best of his or her knowledge, the protocol satisfies the required criteria. Copies of correspondence regarding committee action on a protocol will be sent to the department chair or head. The committee strongly encourages academic departments or units to form their own review committees to pre-review proposals prior to submission to the IRB. Chairpersons may delegate responsibility for departmental review to such a committee but will still receive copies of correspondence regarding the proposals.

Proposal Guidelines and Application

It is incumbent on the individual submitting the protocol to provide a persuasive case for the protocol's approval. The time and resources the committee has at its disposal are limited. Delays will inevitably result when IRB members have questions that are not addressed in the protocol. It is in the author's best interest to provide the IRB with a protocol that is as complete and detailed as possible, especially with reference to the experimental methodology and procedures to be followed, yet confined to **a reasonable number of pages (maximum of five pages, when possible)**.

The IRB is in the business of evaluating risk to participants and counseling authors to avoid or minimize risk. Under circumstances where risk is involved, the IRB must make a judgment of risk versus benefit. When there is risk, it is in the best interest of the author(s) to comment on the degree of risk versus the potential benefit(s) to be derived from the proposed activity.

The signature page should be mailed or faxed to Judy Mills, Department of Psychology and Neuroscience, One Bear Place #97334, Waco, TX 76798-7334, 254-710-6759(fax) other documents emailed to IRB@Baylor.edu for submission to the committee.

THE PROJECT PROPOSAL SUBMITTED TO THE IRB MUST INCLUDE THE FOLLOWING SIX PARTS THAT MAKE UP THE APPLICATION:

Part 1. Signature Page

The Signature Page is a form that asks for information about the author and the project and requires signatures from the faculty advisor and departmental chair or committee. If an expedited review or exemption is applicable, the EXPEDITED or EXEMPTION signature page must also be included.

Part 2. Introduction and Rationale

The proposal to the committee should begin with a description of the research background and rationale (or pedagogical aims) for the project. A compelling case should be made for the use of human subjects. Relevant research (include references in a bibliography), including the author's, should be cited. The question(s) being addressed should be clearly outlined. Any special expertise of the author in this area of research or teaching should be mentioned.

Part 3. Methodology

The methodology to carry out the project/teaching exercise should be described completely and compulsively. Discussion with regards to how many subjects will be used, how they will be recruited, possible risks to subjects (both physical and psychological), method(s) to limit risks, and proposed safeguards to protect subjects' right to privacy should be especially comprehensive. Additionally, research proposals should include a section outlining the method(s) to be used to analyze the data and what avenue will be pursued to disseminate the results of the research project.

Part 4. Informed Consent Form

An Informed Consent Form (ICF) that fully informs potential subjects of the nature of the activity should be constructed. The Checklist for the Informed Consent enumerates issues that should be addressed in the ICF. The form should include a signature blank for the subject. Subjects should be given a copy of the ICF to keep for their records. Investigators who are conducting a mail or telephone survey are not necessarily required to use an ICF. However, a cover letter or an introductory telephone statement explaining the rights of the human subject is usually required and a copy should be submitted.

All protocols using students in classes at Baylor University as subjects must obtain a signed informed consent from the participants. In addition, protocols using minors as subjects must acquire parental consent since the parent bears the responsibility of consenting to their child's participation in a study. IRB approval does not include university approval for protocols involving faculty, staff, and/or students outside of class.

The use of electronic mail as a surveying technology brings out important questions about data security and the confidentiality of participant information. A disclaimer for use of the Internet should be included in the ICF for such purposes (an example is available with the checklist).

The informed consent form should be submitted exactly as it will be used (e.g., correct formatting, on letterhead, etc.) as it will be stamped with an IRB approval date after final approval has been given and returned to the investigator to use in the data collection.

Part 5. Checklist for the Informed Consent

The Checklist outlines all the required information for the ICF. It should be submitted to the committee with those items marked that are applicable to the project and are included in the ICF. An example ICF with explanations is available with the checklist for convenience.

Part 6. Research Instrument(s) to be used (such as surveys, interview questions, etc

If the research study involves the use of a non-standard, newly developed interview or questionnaire instrument (one that has not been previously published), it must be reviewed by the committee. A copy should be submitted as part of the application.

Appendices--If applicable, other information pertinent to the proposal, such as consent letters already received from participating agencies, etc. should be attached to the application.

Contact for Information

Our website may be viewed at *http://www.baylor.edu/IRB* . The forms for submitting a proposal are available there. You may contact the Secretary of the Baylor IRB if you have questions:

Ms. Judy Mills
Email: *Judy_Mills@Baylor.edu*

For questions regarding an individual's rights as a participant or other questions regarding a particular research project, contact the Chair of the Baylor IRB:

Dr. Matthew S Stanford
Department of Psychology and Neuroscience
Email: *Matthew_Stanford@Baylor.edu*

Ms. Mills and Dr. Stanford are located in B309 of the new Baylor Sciences Building, and may be contacted in writing, by telephone, or fax at:

Department of Psychology and Neuroscience
Baylor University
One Bear Place # 97334
Waco, TX 76798-7334
254-710-2811 Office
254-710-6759 fax

Committee Meeting Dates and Deadlines

The Baylor IRB meets monthly during the academic year, September through June. The first meeting of each semester (September and January) is usually scheduled a few weeks after the beginning of classes and the rest are scheduled for the first Monday of the month except when holidays occur.

The deadline to submit proposals for full committee review is Monday two weeks prior to the meeting date except when holidays occur. It is imperative that the deadline be enforced to allow sufficient time for pre-review by the chair and copies mailed to the committee members. Proposals received after the deadline will be submitted for review at the next meeting. Projects to be part of current course work and/or needing to meet deadlines for submission to journals, etc. are not justification for extending the deadlines.

A list of the current meeting dates and deadlines may be obtained from Ms. Mills. This list is available on our website at *http://www.baylor.edu/irb/index.php?id=20759* .

Time Frame for IRB Approval Process

The length of time it takes a proposal to go through the approval process with the IRB can vary greatly. After the committee meets, a letter stating the committee's decision is sent to the author of the proposal with copies to the faculty advisor (if applicable) and the departmental chair. Proposals approved as written are allowed to begin at that time. However, proposals approved with stipulations must not begin until all requirements are met and final approval is given in writing.

Expedited Review: Proposals involving only written, oral, or electronic surveys that do not request any highly personal or sensitive information, and pose only minimal physical and psychological risks to participants may be submitted for expedited review. A minimum of two weeks must be allowed for processing, provided that the proposal is complete upon submission and whether classes are in session so that committee members are available. **An electronic copy is required for proposals undergoing expedited review. Mail signature page to Judy Mills, One Bear Place #97334, Waco, TX 76798-7334 or fax to 254-710-6759.**

It is in the best interest of the investigator to submit a complete application that contains all parts. Any missing items or lack of clarification of important information in the proposal can cause delays.

Office of Human Research Protections

The Office of Human Research Protections (OHRP) is organizationally located in the Office of Public Health Service, an agency within the Department of Health and Human Services. For more information on the OHRP and /or the federal guidelines regarding the protection of human subjects (Title 45, Part 46, of the Code of Federal Regulations) visit their website at: *http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm*

Application to the Baylor IRB
For Review of Research/Activity Proposal

Part 1: Signature Page

1. Name _____

2. Complete Mailing
   Address _____
   EMAIL address _____

3. Position _____

4. Faculty Advisor (if researcher is Graduate Student) _____

5. Is this a dissertation or thesis project (Y or N)?
   (All dissertation/thesis proposals must be approved by the student's committee prior to IRB review)

6. Department/School _____

7. Telephone Number _____

8. Title of the research project/teaching exercise _____

   _____

   _____

9. Please mail/fax this signed form to Judy Mills at One Bear Place #97334, Waco, TX 76798-7334 or fax to 254-710-6759. The application can be downloaded from the following link http://www.baylor.edu/irb/index.php?id=20757 and submitted to the IRB@Baylor.edu email account. If you have questions, or if you would like to see a copy of the OHRP Report on protection of human subjects in research, contact Dr. Matthew Stanford at 254-710-2236.

   _____ _____
   Signature of Principal Investigator Date

   _____
   Signature of Faculty Advisor (required if researcher is a Graduate Student)

10. Departmental Review: _____
    Department Chair or the Chair's Designate

Application to the Baylor IRB
for EXPEDITED Review of Research/Activity Proposal

Attachment to Part 1 (if applicable)

The Baylor University Committee for Protection of Human Subjects in Research (Institutional Review Board or IRB) has agreed to perform expedited reviews of certain research proposals that involve only survey research that poses minimal risk to research subjects. Proposals handled through the expedited review process are held to the same standard as those that go through the normal review process.

To be eligible for expedited review, the proposed research must meet the following three criteria:
(1) the only involvement of research subjects is response to written, oral, or electronic surveys;
(2) the information requested in surveys does not include any highly personal or sensitive information; and
(3) the activity poses minimal physical and psychological risk to research participants.

To make application for expedited review, you must submit an electronic copy from the following link http://www.baylor.edu/irb/index.php?id=20757 and submit to the IRB@Baylor.edu email account. Please mail/fax the signature page to One Bear Place #97334, Waco, TX 76798-7334 or 254-710-6759. If the chair finds that the proposal meets the criteria for expedited review, the proposal will be reviewed by the chair and at least two other members of the IRB. The reviewers may recommend approval, approval with changes and/or stipulations, or review by the entire IRB.

This application must be signed by the (1) principal investigator, (2) faculty advisor (for student investigators), and (3) departmental/school human subjects committee (if one exists) or departmental chair (if no such committee exists).

Title of Research Project/Teaching Exercise_____

_____

Name of Researcher:_____

I have reviewed the research or teaching exercise listed above. In my opinion, this proposal meets all three of the following criteria required for expedited review by the Baylor University Committee for Protection of Human Subjects in Research:

(1) the only involvement of research subjects in the proposed research/teaching activity is response to written, oral, or electronic surveys;
(2) the information requested in these surveys does not include any highly personal or sensitive information (i.e. reports of criminal activity or sexual behavior); and
(3) the activity poses minimal physical and psychological risk to the research participant.

Signature of Principal Investigator _____ Date_____

Signature of Faculty Advisor _____ Date_____
(for student researchers)

Signature of Chair of Departmental or School Human Subjects Committee (if one exists) or Departmental Chair (if no committee exists)_____ Date_____

Application to the Baylor IRB for EXEMPTION from Review

Attachment to Part 1 (if applicable)

Research activities in which the only involvement of adult human subjects will be in one of the following categories are exempt from IRB review;

1. Anonymous surveys or questionnaires
2. Research involving the study of existing data, documents or records if these sources are publicly available or if the information is recorded in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

These exemptions do not include studies involving minors as participants or archival data previously gathered from minors. The Baylor IRB chair, in consultation with the IRB as deemed necessary, retains final judgment as to whether a particular activity is covered by this policy. Investigators who believe their study is exempt from review must submit a completed proposal to the IRB chairman to receive an exemption waiver.

To make application for exemption from review, you must submit an electronic copy from the following link http://www.baylor.edu/irb/index.php?id=20757 and submit to the IRB@Baylor.edu email account. Please mail/fax the signature page to One Bear Place #97334, Waco, TX 76798-7334 or 254-710-6759.

This application must be signed by the (1) principal investigator, (2) faculty advisor (for student investigators), and (3) departmental/school human subjects committee (if one exists) or departmental chair (if no such committee exists).

Title of Research Project/Teaching Exercise_____

_____

_____

Name of Researcher:_____

I have reviewed the research or teaching exercise listed above. In my opinion, this proposal meets the criteria required for exemption from review by the Baylor University Committee for Protection of Human Subjects in Research:

Signature of Principal Investigator _____ Date_____

Signature of Faculty Advisor _____ Date_____
(for student researchers)

Signature of Chair of Departmental or School Human Subjects Committee (if one exists) or Departmental Chair (if no committee exists)_____ Date_____

Part 2: Introduction and Rationale

Describe below (or on a separate paper) the research background and rationale for the project. Make a compelling case for the use of human subjects. Include relevant research (including your own) in a bibliography. Clearly outline the question(s) being addressed, if authoring a research proposal, and mention any expertise you have in this area of research or teaching. (Attach more pages if necessary--however, **Parts 2 and 3 combined should be confined to a reasonable number of pages, five maximum,** when possible.)

Part 3: Methodology

Completely and compulsively describe below (or on a separate paper) the methodology to carry out the project/teaching exercise. Include how many subjects will be used, how they will be recruited, possible risks to the subjects (both physical and psychological), method(s) to limit risks, and proposed safeguards to protect the subjects' right to privacy. Research proposals should also include a section outlining the method(s) to be used to analyze the data and what avenue will be pursued to disseminate the results of the research project.

Part 4: Informed Consent Form

Provide below (or on a separate paper), marked "Informed Consent Form," a copy of the informed consent form to be used. It must include all items listed on the Informed Consent Form Checklist that are applicable to your proposal. *Be sure the form is exactly as it will be used (e.g., correct formatting, on letterhead, etc.) as it will be stamped with an IRB approval date after final approval has been given and returned to the investigator to use in the data collection.*

Part 5: Informed Consent Form Checklist

When using humans as subjects in research you must obtain their informed consent. Check each of the following items as they appear on your Informed Consent Form and include this checklist with your protocol: **Go to insert symbol to add the √ by each item.**

____(a) A statement explaining the purpose of the research.
____(b) A statement of the expected duration of the subject's participation.
____(c) A description of the procedures to be followed.
____(d) A description of any reasonable foreseeable risks or discomforts to the subject, including invasion of privacy.
____(e) A description of any benefits resulting from the research, either to the subject or to others.
____(f) A statement that informs subject of his/her right not to be a subject in a research project that is also a teaching exercise.
____(g) A statement informing subject about how his/her anonymity will be guarded; i.e., that their confidentiality will be protected by assigned code numbers, by limitations of who has access to data, by data storage in locked cabinets, by locked computer files, etc.
____(h) A statement that the subject's participation is voluntary, and that his/her refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.
____(i) A disclaimer, if applicable, regarding the use of the Internet to collect data.
____(j) For research involving more than minimal risk, an explanation regarding the availability of any compensation or any medical treatments if injury occurs (if applicable, see OHRP Reports).
____(k) If written informed consent is required, a place for the subject to sign and date the form and a statement that a copy of the signed consent form will be given to the subject for his/her records.
____(l) If the subject is a minor, a statement of parental responsibility in consenting to the child's participation in the study with a place for the parent to sign and date the form in addition to the participant's signature.
____(m) The name, address, and telephone number of the principal investigator of the research project, and his/her affiliation with Baylor University. If the principal investigator is a graduate student, the name and telephone number of the faculty advisor is also required.
____(n) A statement informing subject that inquiries regarding his/her rights as a subject, or any other aspect of the research as it relates to his/her participation as a subject, can be directed to Baylor's University Committee for Protection of Human Subjects in Research. The chairman is Dr. Matthew S. Stanford, Department of Psychology and Neuroscience, One Bear Place #97334, Waco, Texas 76798-7334, phone number 254-710-2236.

Part 6: Research Instrument(s)

Attach any non-standard, newly developed interview or questionnaire instrument (one that has not been previously published) that will be used. Also attach as appendices any other information pertinent to the proposal, such as consent letters already received from participating agencies, etc.

The proposal must be emailed to IRB@Baylor.edu. The signature page(s) should be mailed to One Bear Place #97334, Waco, TX 76798-7334 or faxed to 254-710-6759 for submission to the committee for review.

BIBLIOGRAPHY

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