Ying Tang

IST 659

Prof. Huang

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Project Proposal

1. Business description (20 pts)

Describe the business based on the answers to the following questions. What industry does this organization reside? What products or services does it provide? What are its general business functions? Answering these questions will help you think further of what data need to be stored in the database and what data questions the users commonly ask.

I am planning on developing a project to help the Syracuse University Institutional Review Board (IRB) and individual departments to better organize and manage the institutional research database. My project therefore resides within higher education, and is not for-profit by nature.

There are two integral components to the proposed database. The first component is the IRB. The IRB is an administrative branch of the university. It is an independent committee located within a higher education institution that is designated to review and monitor biomedical and behavioral research involving human participants. One of the primary functions of the IRB is to enforce ethical protocols in human subject research, including protecting the rights of the participants and preventing psychological and physical harm and injury in research.

The IRB mandates that all research involving human subject be approved before actual data is collected. Therefore, researchers who plan on conducting such research should submit an application to the IRB with detailed descriptions of the research procedure, research stimuli, funding sources, collaborations, criteria and methods for participant recruitment, and other relevant information. After the research application is approved, researchers can then proceed to execute the study. The IRB assigns a unique file number to identify each research application, and each file contains specific requirements pertaining to the research project.

Some important information that the IRB database manages and provides includes information about the researchers/staff as well as information about each study project.

Another component of the proposed database is the individual department in which the research is conducted and executed. Each individual department, for example, the Department of Psychology, typically has a subject pool where participants are recruited. Entities involved on the individual department end include – other than researchers and research staff – instructors who provide students with the requirement to participate in research, students who participate in research for credits, and administrative staff who manage the execution of the research projects.

2. Problem statement (30 pts)

Describe the data management problem based on the answers to the following questions. What data management problem are you trying to solve? What is the current solution? Why is the current solution not adequate? Justify the need for new data and databases in support of the business.

Currently, the IRB and the individual departments use separate database to manage research projects.

**The IRB:**

The database management system that the IRB uses is outdated and inefficient.

1) One problem that most of the IRB database management is still paper-based. For example, all materials related to the application are required to be printed out and submitted via campus mail. This is problematic because it is 1) not green; 2) not secure; 3) it makes it difficult to present certain electronic information (such as a website).

2) A second problem seen in the current IRB database management is that information is stored and distributed in a fragmented fashion. To be specific, all communication between the researcher and the IRB after the initial application is submitted via email. All decisions related to the application, including requests for modifications, approvals or rejections, are communicated via separate emails. The direct consequence is that the researchers have to keep track of possibly a string of individual emails across a long time span (possible a few years if a project has been renewed and modified multiple times) to access information regarding the status of their projects. The current difficulty with access to centralized information calls for streamlining and updating the current management strategy.

The IRB has been managing research files in the fashion described above since I have started graduate school four years ago, without any change or update. Therefore, I have not seen any attempted solution to the issues that I presented above. That is why a database management update is very necessary and important.

**Individual Departments:**

The individual department uses a separate system to manage research projects and participant recruitment; for example, the Department of Psychology uses a system called SONA. While such systems have been working quite effectively on their own, the fact that they are separated from the IRB research management system leads to certain problems with management efficiency. For example, one major issue is that the researchers are responsible to report to both the IRB and the individual department regarding the status of the research project, while the IRB and the individual department could communicate directly if information regarding each research project is centralized in one system. Therefore, one advantage of the currently proposed database is that it will serve to bridge the two existing systems, helping to reduce redundant information and consolidate management of research projects on campus.

3. Proposed solution (30 pts)

Describe a potential solution to the data management problem. Describe the project scope by answering the following questions. What business functions will be considered in the proposed system? What functions are considered but not included? Why? Describe the primary business objectives of the proposed system.

Currently, while the IRB office mainly oversees and approves the application of a research project as well as archiving research projects after they expire, the individual departments are in closer supervision of the execution of individual studies. It is logical to design a database management system that integrates the two separate systems. Thus, I am proposing to create such a database system to streamline review, management, and storage of information related to human subject research projects in an institution. This database will contain important information about the life cycle of a research project: the application, execution, and archival of a research study.

Main functions considered in the proposed system will be:

1. For the IRB: To store and manage information about the researcher, staff involved in the study, as well as information about the research studies.
2. For the researchers: To submit, manage, and access information about their research projects.
3. For the administrative staff in individual departments: To monitor active research projects, supervise participant recruitment.
4. For the instructors in individual departments: *(These instructors may offer students the opportunity to participate in research for credits towards their classes; therefore, the instructors need to have access to students’ participatory record)* To monitor students’ participant in research projects.
5. For the students: To be able to sign up and participate in research projects, to be able to view their research participation credit.

Entities and Corresponding Attributes:

1. IRB Reviewers: Name, Title, Disciplines
2. Principal Investigator (Researcher): Name, Department, Address, Contact Information, CITI Training Qualification, Research Projects
3. Staff: Type (grad student or undergraduate RA), Name, Department, Address, Contract Information, CITI Training Qualification, Research Projects
4. Research Projects: Title, Type, Application Date, Duration of Validity, Expiration Date, PI, Staff, Number of Participants, Stimuli, Location, Time, Open Slots.
5. Instructors: Title, Class, Credit Offered
6. Students: Name, Class, Instructor, Research Project Participated In, Credit, Total Credit Earned, Absences

Because this is not a real business per se, there are many aspects of business functions that do no apply to the current project (such as finance, HR, etc). However, there are certain technological support aspects that are related but not necessarily included in the proposed database system. For example, the actual CITI training program (the program that provides ethical protocol training to researchers and research staff) will be another stand-alone system. However, certain pieces of information from the CITI program (pass or fail of the researchers and staff) will be stored in the current database.

4. Users (20 pts)

Who are the users of your database system? Do all of them have equal access to the data? What data questions do they need to answer by querying the database?

The users of my database system will include the IRB reviewers, researchers, staff, instructors, students, as well as administrative staff.

1. The IRB reviewers should be able to have access to all research projects, researchers and staff. Some data questions that IRB reviewers might want to answer by querying the database are: A. What are the details of the projects? Should I approve or reject it or request modifications? B. Do researchers and staff of the research project meet the CITI training requirements? C. Have the researchers submitted the requested modifications or supplemental materials?
2. The researchers should only be given rights to access information regarding their own projects and the staff involved. Certain staff (e.g., graduate student) may also access information of the research projects that they are involved in. Researchers and staff may want to query the database because they want to find out about: A. expiration date of the research project; B. duration of the CITI training; C. status of their research project application; D. modification requests for their projects; E. Participation enrollment in the research study.
3. The instructors of courses in individual departments will have access only to students in their class who have participated in research. The instructors need the information to assess the amount of the research participation that a student has done, in order to assign course credits.
4. The students will only have access to active research studies that are open and available for sign-up. They may only be able to view the basic information of the studies (description and research contact information, for example), location and time. They may also be able to access their own participation record.
5. The administrative staff at the IRB and in the individual departments should have access to all research projects, researchers, and staff. The administrative staff may want to access the information because they need to manage the research projects, send out notifications to the researchers if the validity of their project or CITI training has expired, supervise the participant enrollment, manage the availability of the research studies to the students, grant access authorization to students and instructors, and others.