**IBC Biosafety: Registration System**

**Design Overview Document**

***CD6 Final v1.1***

11-19-2012

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12. **Introduction**

**1.1 Overview**

The IBC (Institutional Biosafety Committee) formerly used Microsoft Access to store information, but due to the system conversion from the eRA (Electronic Research Administration) for the TRA (Temple University Research Administration), Microsoft Access was disabled. The information storage reconstruction for other departments happened more than five years ago and the Institutional Biosafety Committee was the only regulatory committee that was not given a place in Electronic Research Administration. The IBC record keeping remains encumbered, using paper and excel sheets to document their information. They need a complete information system including data entry and a query system with a database to store their biosafety project information. Paper overhead is too cumbersome. Mary Pultro, the Institutional Biosafety Committee Coordinator will be the sole administrator of the system. Since the current process is not inducive to quick and efficient processing, the system will not be changing the business process but will be drastically increasing speed of the data handling.

**1.2 Background**

The Institutional Biosafety Committee (IBC) is responsible for the regulation and monitoring of all University research that involves recombinant DNA, infectious agents, and other biohazards. For a new research project to be acknowledged by the IBC, an electronic form with the project information must be completed and submitted to the IBC office. The IBC administration assigns a biosafety registration number to this project while recording the project information within the IBC Registration Log Book. Within the current business operations, the IBC Coordinator records their project information on paper and Microsoft Excel Spread sheets. This process is generally sluggish, tedious, and cumbersome. Retrieving information for query and auditing purposes remains inefficient. The benefits of a new system to house the project record data will include a number of enhancements specializing in accelerating the already stable business process.

The system capabilities encompass a user interface, a database for the biosafety project log information, report generation, document attachment storage, a querying system, and a notification system. An intuitive user interface ensures quick navigation through different functionalities. Querying specifics on the housed information produces data sets which can drastically reduce the current retrieval time. These specifics can be used to generate reports according to the information acquired. Attaching documents to already recorded logs enables the IBC coordinator to store an increasing amount of project information than currently possible. With a notification system, the IBC coordinator is able to set up project renewal times and dates for the system to notify them respectively.

1. **Requirements**

**2.1 Functional Requirements**

The system shall do the following:

* Enter New IBC Biosafety Project

IBC Biosafety Project record is created by the IBC Coordinator after receipt of supporting project documentation. A sequential biosafety registration number is generated. The IBC Coordinator can populate all fields in record and the system saves record.

* Display / Query Project Records

The IBC coordinator has quick retrieval capabilities. The system displays specific queried project records and fields within. For example: Date, PI, Project name, Biohazard type, and plan. The IBC Coordinator can browse all projects in the log and choose specific fields to be searched.

* Update Project Record

The IBC Coordinator receives an amendment to project which might include: PI, Biohazard, date, or title change. The IBC Coordinator may apply changes when editing the data and then saving the changes.

* Notification

The IBC Coordinator may choose to automatically set a notification for its yearly renewal. The IBC Coordinator may also manually set notifications.

* Close / Archive Record

After project completion, a project is required to be archived or deactivated. The IBC Coordinator updates the project status by editing the project as closed.

* Generate Report

When viewing the search results from querying project records, the IBC Coordinator may select these projects using checkboxes. This will designate the fields selected capable to be printed for a report.

**2.2 Nonfunctional Requirements & Environmental Design**

The IBC Biosafety Registration System can simply be hosted and personally managed through a webhost. For a cheap affordable cost, web hosting can provide security packages and data backup features which can easily backup your information. This will provide the IBC Biosafety Registration System to be accessible on the web.

The client may also consider the TUcloud which enables Temple departments to purchase computing and storage space on Temple’s centrally managed servers. The servers are administrated by the Computer Services Center that resides in Temple’s main data centers. Departments can use the TUcloud service for web servers, file servers, or application servers.

TUcloud frees up department resources from having to plan, purchase hardware, and perform day-to-day server maintenance, such as software patches and backups. With TUcloud, it is possible to purchase only the required services. If the system requires an addition, purchasing additional computing power and storage space is simple. Since TUcloud owns the hardware, this avoids having to commit to a major hardware purchase.

TUcloud is a cost-effective alternative to purchasing departmental servers. This frees up IT staff from managing departmental servers. The price is based on the type of services required which can be easily expanded, if necessary.

1. **Assumptions and Constraints**

**3.1 Assumptions**

While careful consideration has been given to all aspects of the system design, a number of assumptions have been made and are under various stages of verification.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| No. | Assumption | Validated by | Status | Comments |
| 1 | The IBC registration log system will store all of its associated data on the same machine as the user interface. | IBC coordinator | Open | It is understood that permission has not been received to deploy a system which interacts over the local network. Web hosting or cloud storage could be a feasible alternative. |
| 2 | The IBC coordinator will be the only user of the system. | IBC coordinator | Confirmed | The issue has been discussed during a meeting with IBC coordinator and is still awaiting final verdict. |

**3.2 Constraints**

The following are constraints which currently have an impact on the system design:

|  |  |  |  |
| --- | --- | --- | --- |
| No. | Area | Constraints | Comments |
| 2 | Departmental Permissions | Backup system is limited to a local external hard drive unless the IBC department allows the use of Temple Servers or other external storage services. | Backup system could potentially be in a separate location within the local area network or even on a cloud service provider with proper permissions. |

1. **Risks**

The following are Risks and their associative controls which currently have an impact on the project design:

|  |  |  |
| --- | --- | --- |
| No. | Risk | Control |
| 2 | The IBC coordinator will need additional system support after the availability of the project team has expired. | Extensive documentation will make it possible for a separate party to continue servicing and expanding the system. Terms for extended support will be discussed at a future date. |
| 3 | Data is lost due to hardware failure, user error, or software failure. | A local backup system will be in place for data recovery. Additional backup solutions could be possible with budgetary considerations or departmental permissions. |

1. **Design Overview**

**5.1 System Interface**

The purpose of the system interface is to ensure the intuitive usability of the IBC Biosafety Registration system. The system interface will be a user interface design which will focus on the user’s interaction with the database and minimal human interaction required.

The system interface uses a keyboard, mouse, and scanner as input. The keyboard is used to enter relevant data into the Registration System. This data is for new records or record updates. The mouse’s purpose is to allow the user to easily navigate the user interface. The scanner will be used to scan relevant documentation for each biosafety project. The system interface’s output includes email notifications and reports. Notifications can be created manually or triggered automatically.

**Input:**

* Scanner: to scan and attach documents relevant to each project
* Keyboard: to enter relevant data into each project
* Mouse: enables the client to navigate the system

**Output:**

* Internal outputs: notifications
* External outputs:
  + Detailed reports: report about a specific project
  + Summary report: quarterly and annually report
  + Exception reports: reports about a project that is suspended or closed
  + Executive reports: reports for department chair.

**5.2 Conversion**

IBC biosafety project data initially exists in completed registration forms. These forms include the IBC’s *Biosafety Level 1 Registration Form, Biosafety Registration Form, Biosafety Registration Addendum: Whole Animals, Protocol Amendment Request,* and *Annual Protocol Renewal Request*. The IBC Coordinator will convert this written data by manually entering it into the IBC Registration System using mouse, keyboard, and scanner inputs. The IBC Coordinator can use the system to convert this data into reports by specifying system preferences and query data.

**5.3 Security**

The information that will be stored in the new IBC Biosafety Registration System will be inherently confidential in nature. However, the goal of maintaining this system’s security is made easier by its stand-alone environment. The current system design reflects security in the following aspects:

|  |  |  |  |
| --- | --- | --- | --- |
| No. | Security Concern | Control | Comments |
| 1 | Unauthorized access to the system is attempted. | User name and password will be required to access the system. | The credentials will be managed by the system administrator. |

**5.4 Client Commitment**

In order to provide a functional system for the IBC Biosafety Registration System, communication between the IBC Coordinator and the project team must be established. Testing data and resources will occur once prototype has met the client’s needs. Throughout the course of the project we will have discussed and developed a prototype before the following semester begins.

The spring 2013 semester will include testing to assure that the system will be functional for the final product. Numerous client meetings must be established to assure requirements are met with the system. Towards the end of the development phase, the user-friendly interface would meet client specifications. If training is needed for the IBC Coordinator to use and maintain the system, he or she may refer the user manual that will be provided towards the end of completing the system.

**5.5 Testing**

* **GUI software testing** – The process of testing the part of the system that uses a graphical user interface to ensure is meets the prototype functionality.
* **Usability Testing** – Determine whether the user interface is easy enough for the IBC administrator navigate without confusion. The prototype will be presented to the IBC coordinator for evaluation and any changes will documented.
* **Active Testing** – Type of testing consisting of introducing test data within the database to ensure the data storage properly houses the record registration log information. This needs to ensure that data handling will not slow the system down as more data is introduced.
* **Unit testing** – Testing the individual units of source code after they are inserted for use. Will be conducted during programming. This involves the longest testing time as more code is introduced.
* **Security Testing** – A process to determine that the system protects the record log information. The windows LSAS might be sufficient enough protect the offline database.
* **User Testing**– A type of testing which requires the user to evaluate the functionality of the system and its capabilities in relation to the user’s requirements.

1. **Documentation**

**6.1 User Manual Summary**

* Login: Enter your Username and Password
* Specify Displayed Fields: Checked field checkboxes will automatically display
* Generate Reports
* Add Project: Enter the available project information into the empty record fields
* Edit Project: Select a project and enter the new project information into the applicable fields
* Notifications: multiple recipients, dates, and content.
* Archive Project

1. **Budgetary Considerations**

Although the IBC Biosafety Registration System is currently designed to be a stand-alone system, a few options have been provided for consideration. Of the available options to consider, the best recommendations for an inexpensive and low cost solution that can provide all the necessary features such as backups and security are as follows:

# Web hosting:

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| No. | Web Host | Price | Setup | Domain | Disk Space | Data Transfer | Money Back |
| 1 |  | $3.95/month | Free | Free | Unlimited | Unlimited | Anytime |
| 2 | . | $2.95/month | Free | Free | Unlimited | Unlimited | Anytime |
| 3 |  | $2.95/month | Free | Free | Unlimited | Unlimited | 90 Days |

# Features

# Free Setup

# Free Domain

# Unlimited disk space

# Unlimited data transfer

# Backups and Security (may cost extra)

* 1. **TUcloud**

Three packages:

**Departmental File Storage (TUvault)**

|  |  |
| --- | --- |
| Plan Name | TUvault |
| Price Per Month | $0.24/GB |

Features:

* Clustered network-attached storage (NAS) servers
* No need to have OS overhead or costs
* No setup fees, pay month-to-month
* Grow disk space on demand
* Automated daily backups are included in price

**Virtual Server Hosting**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Plan Name | TUcloud 2\_30 | TUcloud 2\_60 | TUcloud 4\_30 | TUcloud 4\_60 |
| RAM | 2GB | 2GB | 4GB | 4GB |
| Storage\* | 30 GB | 60GB | 30GB | 60GB |
| Price Per Month | $42.88 | $48.88 | $46.88 | $52.88 |

Features:

* Two data centers for disaster recovery capabilities
* High-availability and clustering support
* Multiple virtual CPU capabilities
* Snapshots for upgrades
* Choice of Windows or Redhat Linux
* Raid 5 SATA disks. Fiber disks available upon request
* No setup fees, pay month-to-month
* Grow disk space, memory, or virtual CPU on demand
* Backups are included in the above pricing.

**Additional Storage for Virtual or Physical Servers**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Plan Name | TUcloud SATA | TUcloud SATAm | TUcloud Fiber5 | TUcloud Fiber5m | TUcloud Fiber10 | TUcloud Fiber10m |
| Disk Type | SATA | SATA | Fiber | Fiber | Fiber | Fiber |
| Raid Level | 5 | 5 | 5 | 5 | 10 | 10 |
| Data Mirror | No | Yes | No | Yes | No | Yes |
| Price Per Month | $0.20/GB | $0.24/GB | $0.33/GB | $0.50/GB | $0.43/GB | $0.69/GB |

Features:

* Two data centers for disaster recovery capabilities
* High-availability storage area network (SAN) and clustering support
* Fiber or iSCSI connections
* SATA or Fiber disks
* Raid 5 or Raid 10 solutions
* Snapshots of data for upgrades or copies
* Data mirroring between data centers depending on plan
* No setup fees, pay month-to-month
* Grow disk space on demand
* Backups are included in the above pricing.

1. **Support**

After completing the IBC Biosafety Registration system, free support access will be given up to the end of August 2013. Anything regarding support post end of August will be discussed close to the end of completion of the system. Once the client is satisfied with the system set to specifications, the project team and the IBC Coordinator will engage in a support agreement that will begin post August 31st 2013.

1. **Summary**

The IBC Biosafety Registration System will drastically improve upon the current business process used by the IBC coordinator. The new system will increase productivity and improve information security. The ability to keep all related documentation linked together within one central interface will increase information accountability for auditing purposes. By December of 2012, the system design phase will be completed. A final presentation along with a complete documentation binder will be available for review.

During the spring 2013 academic semester, the IBC Registration System will go into the development phase. This will remain an iterative process which includes the IBC coordinators input. Throughout the development phase, testing will be performed to ensure that the functionality meets the design specifications. Implementation will be complete by April of 2013 in order to give the IBC coordinator time to familiarize and test the final product.

1. **Appendix**

**10.1 Abbreviations and Acronyms**

|  |  |  |
| --- | --- | --- |
| 1 | IBC | Institutional Biosafety Committee |
| 2 | PI | Principle Investigator |
| 3 | NIH | National Institute of Health |
| 4 | CDC | Center for Disease Control |
| 5 | IACUC | Institutional Animal Care and Use Committee |
| 6 | IRB | Institutional Review Board |
| 7 | BRF | Biosafety Registration Form |
| 8 | BRN | Biosafety Registration Number |
| 9 | ACUP | Animal Care and Use Protocol |
| 10 | EHRS | Environmental Health and Radiation Safety |
| 11 | rDNA | Recombinant DNA |
| 12 | RAC | Recombinant DNA Advisory Committee |
| 13 | ABSA | American Biological Safety Association |
| 14 | APRR | Annual Protocol Renewal Request |
| 15 | BSL | Biosafety Level |
| 16 | BSC | Biosafety Cabinet |
| 17 | ECP | Exposure Control Plan |
| 18 | SOP | Standard Operating Procedures |
| 19 | SBA | Select Biological Agent |
| 20 | CEMS | Chemical Inventory and MSDS |
| 21 | SPAF | Sponsored Projects Approval Form |
| 22 | DOT | Department of Transportation |
| 23 | BMBL | Biosafety in Microbiological and Biomedical Laboratories |
| 24 | OBA | Office of Biotechnology Activities |
| 25 | RG | Risk Group |
| 26 | ERA | Electronic Research Administration |

* CDC/NIH/OBA/BMBL/EHRS: can be found on IBC quick reference guide
* BSC/BSL/RG/SOP/ECP: can be found on Biosafety Registration form
* ACUP: can be found on Institutional Biosafety Committee Protocol Amendment Request
* CEMS/SBA/DOT: can be found on Temple University’s Policies and Training form

**10.2 Client Meeting Notes**

*Meeting 1:*

* IBC Chair: read and review project registration
* ERA: read and review project registration
* IBC Coordinator (primary system role): read, review, update, add, remove
* PI (researcher and project applicant): there can be multiple
* IBC Coordinator uses Excel sheets to track IBC Biosafety Projects
* IBC Coordinator is expressed in the Registration Log
* IBC and IRB needs BRF overview (at glance): queries/reports (Biohazards per project/personnel)
* BRF includes the most IBC protocols
* IBC Coordinator wants to track the approval status and IBC protocol processes of the projects
* IBC Coordinator wants to include attachments
* Projects have an annual renewal
* Suggested Scope - Project Proposal: Protocol Amendment, Training Validation, User Administration Structure, Reminders
* PI presents project at IBC staff Seminar

*Meeting 2:*

* IBC Coordinator isn’t sure if she has the permission to use the system
* System/Use Cases
  + “Stand alone system”
  + BRF number is generated
* Query/Report: satisfied with a few (“1-3”) fields
  + Definite: Biohazard, PI, NIH Category
  + Maybe: Department, Recumbent DNA Projects
* Notification System
  + “It doesn’t have to be complex”
  + With multiple recipients - “most valuable for renewals”
  + The project is archived/closed when the project’s approval is differed or the project has expired.
* Project record needs: biohazard, place, PIs, title, BRF number, submission date, NIH Category, approval status. approval date, and plan date (IBC Committee review)
  + Maybe needs: IACUC number, IRB number, PPe, Comments, and attachments.
* Registration does not always need to be received by full committee
* “JR” – registration is reviewed only by the IBC Chair
* Design Review – IBC full committee review not necessary
* Approval: Approved, Conditional, Deferral
* Enter project record despite Approval status

Project Archived/Closed: wants to include the reason it closed.

1. **Approvals and Sign Offs**

**Date: \_\_\_ /\_\_\_ /\_\_\_\_\_\_**

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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**Matthew Shirley**

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