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Project Title: Biosafety Information Online (BIO)

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I. Project Leaders and Team Members

Biosafety Information Online (BIO) was developed through the collaboration of a talented technical team and a strong and dedicated UC-wide functional workgroup. The key to the success of this project was the partnership between the individual experts from each campus and the development team, a partnership that continues as the system is enhanced and rolled out to additional UC campuses.

**Project Leadership**
- Safa Hussain, Executive Director, Information Technology Services, UC Davis
- Brenda Wong, Biosafety Officer, EH&S Research Safety Division, UC San Diego
- Anitra Willis, Associate Director, Resource Management Planning IT Services, UC San Diego

**Information Technology**
- Andria Way, Scrum Master UCD
- Catherine Keeley, Project Manager UCD
- Stefan Tomic, Lead Developer UCD
- Dave Mannion, Lead Developer UCD
- Walter Sysko, Developer UCD
- Carolyn Germino, Developer UCD
- Sowmya Sekar, Developer UCSD
- Joe Bair, QA Analyst UCD
- Jessica Eisner, QA Analyst UCD
- Diana Cox, Manager Project Management Office UCD
- Lisa Johnston, Quality Assurance and Design Manager UCD
- Will Oleksy, Interim Program Manager UCD

**UC Wide Functional Workgroup**
- Brenda Wong, Workgroup Chair UCSD
- Philip Barruel, Product Owner UCD
- Sean Barry, UCD
- Carol Kent, UCSD
- Jamie Bishop, UCSB
- Edgar Romo, UCR
- Nasr Gergis, UCR
- Krystyna Kozakiewicz, UCB
- Monica Lurtz, UCM
- Peili Zhu, UCSF
- Stacy Kraemer, UCLA
- Karianne Terry, UCSC
- Ken Smith, UCOP
- Sheila Hedayati, UCI

**Executive Sponsors**
- Cheryl Lloyd, Interim Chief Risk Officer, University of California Office of the President
II. Summary
Biosafety Information Online (BIO) is an online application that will allow the various University of California campuses to manage and document Biological Use Authorizations (BUAs). UC principal investigators must obtain a Biological Use Authorization (BUA) from their campus Institutional Biosafety Committee (IBC) before conducting research, teaching or related activities that involve recombinant DNA, infectious agents or other biohazardous materials. BUA applications used to monitor for regulatory compliance and help ensure safety by the biosafety groups and Institutional Biosafety Committees (IBC) for each campus.

Working with UC San Diego and a UC wide functional workgroup, Information Technology Services was able to build upon the legacy UC San Diego system to meet the needs for all UC institutions while adding enhancements to increase campus efficiencies and promote safety and regulatory compliance. BIO promotes standardized and streamlined biosafety processes across the UC system and replaces labor intensive campus specific processes. Additionally, the infrastructure overhead (servers, development teams, customer support, etc) for a technology product is supported centrally by IT Services for all UC campuses, alleviating the need for each campus to support an additional technology product.

Some of the system highlights are:
- Allows researchers to apply for, manage, amend and renew BUAs online
- Provides a secure site from which BUAs can be accessed by research staff, authorizing IBC personnel, and EH&S monitors
- Standardizes terms and descriptions used in applications
- Gives researchers a campus-appropriate, risk-based Exposure Control Plan
- Enables authorized research staff to conveniently refer to their lab’s approved BUA
- Allows access for the campus Institutional Animal Care and Use Committee to establish work standards and facility requirements for BUAs involving animal subjects
- Automates renewal reminders

A staging test environment can be accessed here: https://ehs.ucop.edu/bio-staging/

III. Project Description
Background
The University of California is one of the largest biological research institutes in the country conducting more than 2,800 studies each year which require a BUA, per the US Biosafety Officer Survey of March 2012. Attempting to leverage the “Power of 10”, a concept stating that, by working with all ten campuses and the 5 medical centers the University of California can develop one system that will meet the needs of all and help standardize Biosafety programs and compliance reporting across the various campuses. Using this approach the IT Services development team was able to leverage the existing BUA system at UCSD, along with campus infrastructure, to create an enhanced system that can be used as a resource at all of the UC campuses and medical centers. Working with the workgroup and developers from the UCSD team, IT Services was able to build upon their success by adding:

- Single sign on authentication for people from any UC campus
- A role management system that supports multiple campuses
- Automated building feeds for UC campuses
- Human Gene Transfer Clinical Trials
- National Institutes of Health (NIH) Guidelines for Research
• A “Risk Assessment” section in the BUA
• Automated generation of PDF reports

• Bloodborne Pathogen Training renewal notifications
• Additional agents such as Plant Material
- Standardized BUA application questions that meet the needs of all UC campuses.
- Customized Exposure Control Plans (ECP) for each campus.
- Additional security roles for EH&S Staff

This multi-tiered project was released to UCSD in July of 2012 followed by ongoing enhancements based on feedback from the users, and preparation for deployment to other adopting campuses such as UC Davis in June 2013 and UCB and UCSC shortly after.

IV. Innovative Design or Features

Designed with flexibility in mind, the BUA application was developed with open source framework and is scalable to accommodate change when new or revised regulatory requirements are issued. The BUA Web application provides a secure and collaborative resource for conducting essential BUA business processes and internal controls. In creating the online system, preparation was taken to develop a framework and utilize technology that would support future innovation and business regulatory compliance need.

Two systems operate within the BIO application: the Biosafety Information Online web application and the Kuali Rice system. Both systems are hosted by the San Diego Supercomputer Center. The systems leverage UC Trust single-sign-on (SSO) for user authentication. Individuals authenticated by SSO have access only to their campus data, with permissions based on their role within the system.

- Biosafety Information Online – An online web application developed in Java leveraging the Struts framework and an Oracle database back-end.

- Kuali Rice – An online web application that serves as a repository of common data used across many systems. Rice is a middleware application developed by the Kuali Foundation, a consortium of 72 colleges, universities, and private institutions nationwide.

The technical aspects used to develop the system are:

- Enterprise Oracle Database
- Apache Tomcat Application Servers
- Apache HTTPD Proxy
- Linux Kernel-based Application Servers
- IBATIS and Hibernate ORM (Object Relational Mapping)
• Enterprise Spring Beans
• Spring Batch, Spring Integration
• Quartz Scheduling Engine
• Jmeter Load Testing
• WatchFire AppScan Security Scanning
• jQuery User Interface
• JSP (Java Server Pages)
• Java/J2EE Platform
• Apache Struts Web Framework
• Shibboleth – Federated Identity and Access Management
• Kuali Rice Middleware Supporting Identity Management, Role-Based Authentication, and Data Management
• Dedicated Run-time Report Engine
• Agile Methodology and Weekly Deployments to Production
• Daily UC-wide Personnel Data Upload
• Daily UC-wide Building and Room Usage Data Upload

V. BIO Impact

Efficiencies
• The information provided by the researchers when completing their BUAs will populate the databases used by the Biosafety Office to create reports that describe their program.
• Centralized data and reporting for biosafety staff across all campuses. Using a central database, all campuses share Biological Agents and Exposure Control Plans. This central repository provides new campuses implementing BIO with a library of microbial agent-specific exposure control plans. By allowing Biosafety staff at the campuses the ability to maintain this information the data is kept up to date and correct for all campuses. The development team is also working on implementing customizable ECP’s for each campus to accommodate the diversity and specialization at the individual schools.
• Decreases development costs. One system for all ten campuses and the medical centers decreases development costs considerably. These cost savings are increased by reducing the need for each campus to host the system locally; it is instead centralized at San Diego Super Computing Center.
• Centralized support. The IT Services ERM Help Desk supports the application for all campuses.
• One development team is responsible for all bug fixes and enhancements ensuring that all campuses remain up to date with the latest version of the application.

Safety
• The system helps ensure better compliance with the NIH Office of Biotechnology Activities "NIH Guidelines for Research Involving Recombinant or Synthetic Nuclein Acid Molecules."

Customer Satisfaction as of January 2013

Ticket Responses
93% of tickets addressed within Service Level Agreement(SLA) Duration

“...I anticipate that the BIO application will benefit our program a lot and am really looking forward to using it. I am very satisfied with the development team. The development team is a group of very smart, talented, and dedicated people. I am amazed with the speed that the developers address issues and implement feature requests. The project manager is very organized and helps keep the functional workgroup productive. Since I am copied on BIO incident reports (issues or bug tickets) I do witness the team’s responsiveness and dedication to good customer service.” – Philip Barruel Biosafety Staff UC Davis