

Duke Surgery Research Central:
an open-source Web application for the
improvement of compliance with
research regulation

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Why DSRC?

- Integrity of the research process.
- Minimization of lawsuits.
- Faculty member concerns.
- High cost of regulatory compliance
(32% of time & \$2000 per subject)

Past Projects

- Early 1990s, NLM funding for Integrated Academic Management Systems (IAMS).
- eGrants (U of Cincinnati): 200% increase in funds for educational research, etc.

Goals

- To allow researchers to visualize the administrative progress of their projects
- To allow research administrators to track all projects.
- To generate reports that would establish the current compliance status of individual researchers

Design Objectives

Reasonable and appropriate?

- ⦿ Researcher interface should be simple and intuitive in order to meet the requirements of users with different levels of computer literacy.
- ⦿ The application should run on an Intranet within the campus firewall to enhance protection against security breaches.
- ⦿ Researchers should be informed about the existence of new tasks assigned to them through a variety of mechanisms, including e-mail and RSS (real simple syndication) feeds.
- ⦿ Tasks assigned to users should have a clear sequence of activities to be followed by the researcher. At a minimum, they should have instructions on how to complete the regulatory activity, provide instructions and electronic templates for that task, provide an interface for document submission, and allow users to inquire research administrators about the status of their administrative tasks currently in-process.

Design Objectives

Reasonable and appropriate?

- ◎ The application should store additional information that might be of value to researchers, including links with information about research opportunities, tools to search for available number of patients for prospective research, and other applications that will change the image of a regulatory site from a burden into a service to the researcher.
- ◎ Research administrators should have the ability to track the times of completion of researchers stratified by department, project name, leader, task, deadline date, research administrator in charge, and principal investigator.
- ◎ Research administrators should be able to delegate tasks that are commonly associated grouped in "bundles." By grouping tasks that can be assigned through a single command, task bundles are time efficient for research administrators.

DAO Model

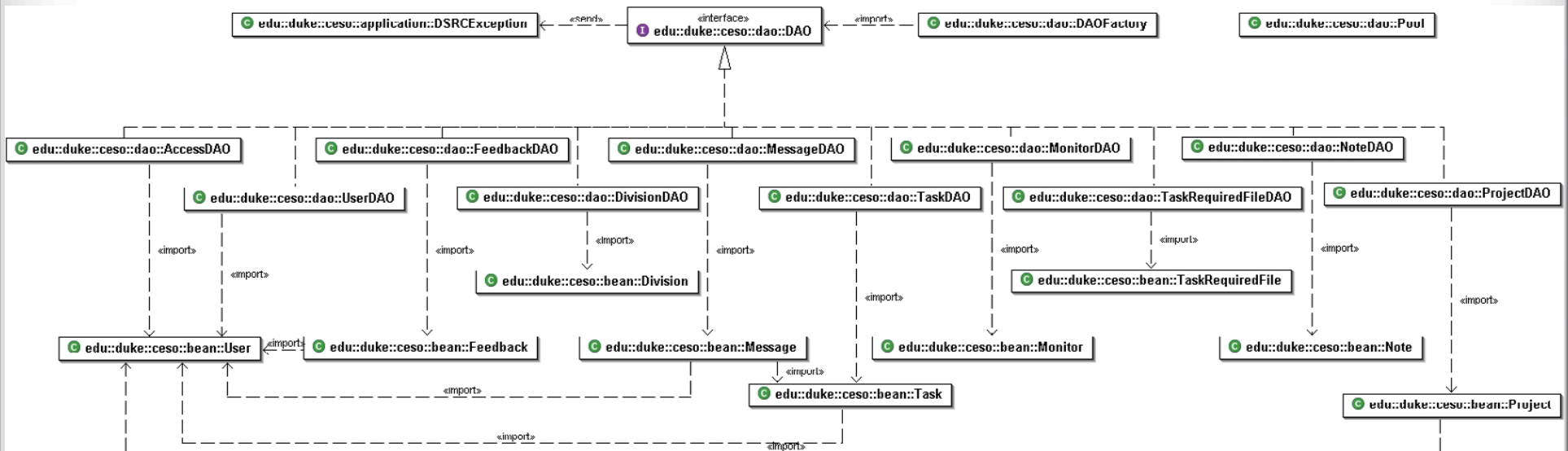


Figure 1
UML Class Diagram that implements the Data Access Object design pattern.

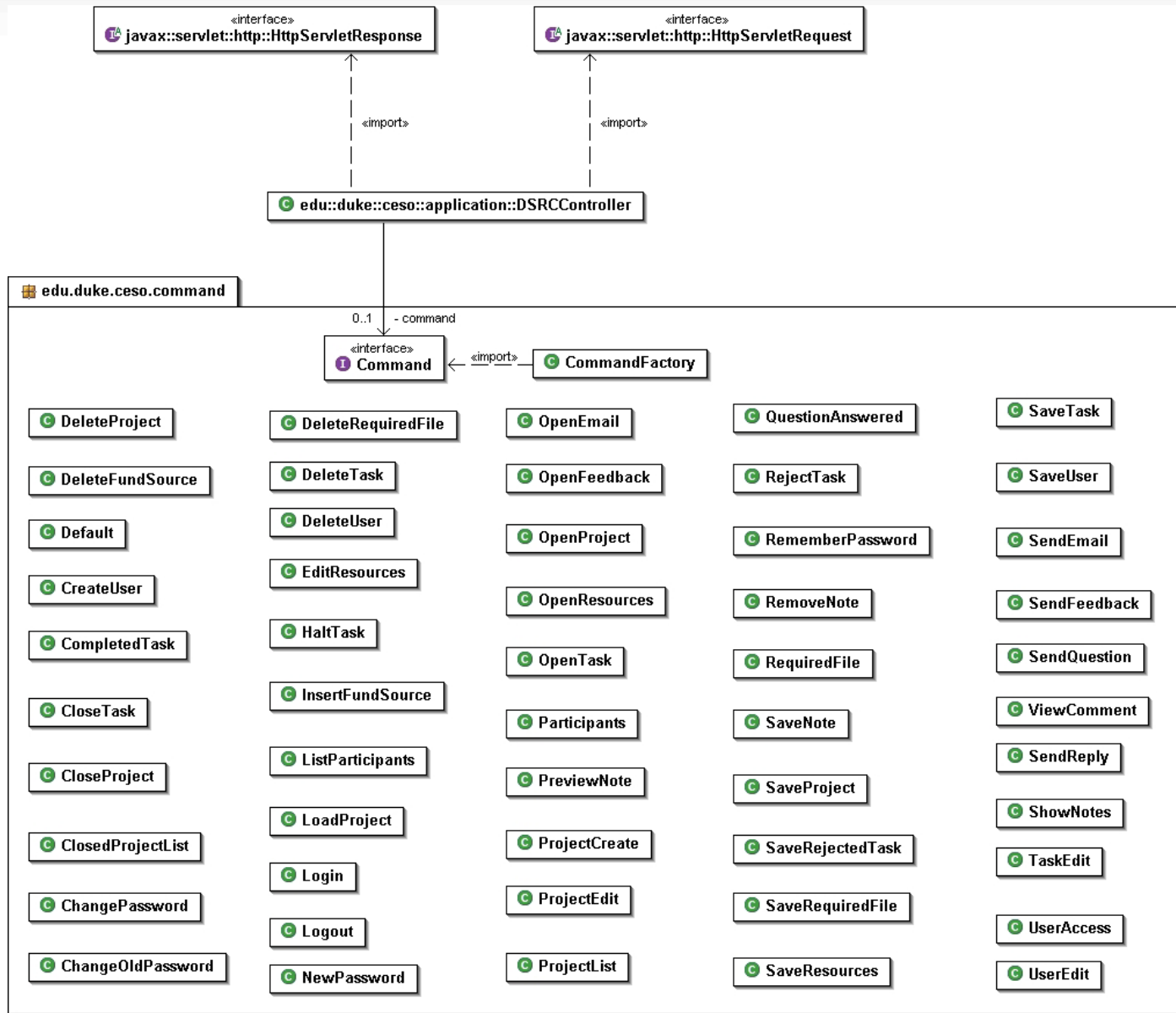


Figure 2
UML Class Diagram that implements the Command design pattern.

Model & View

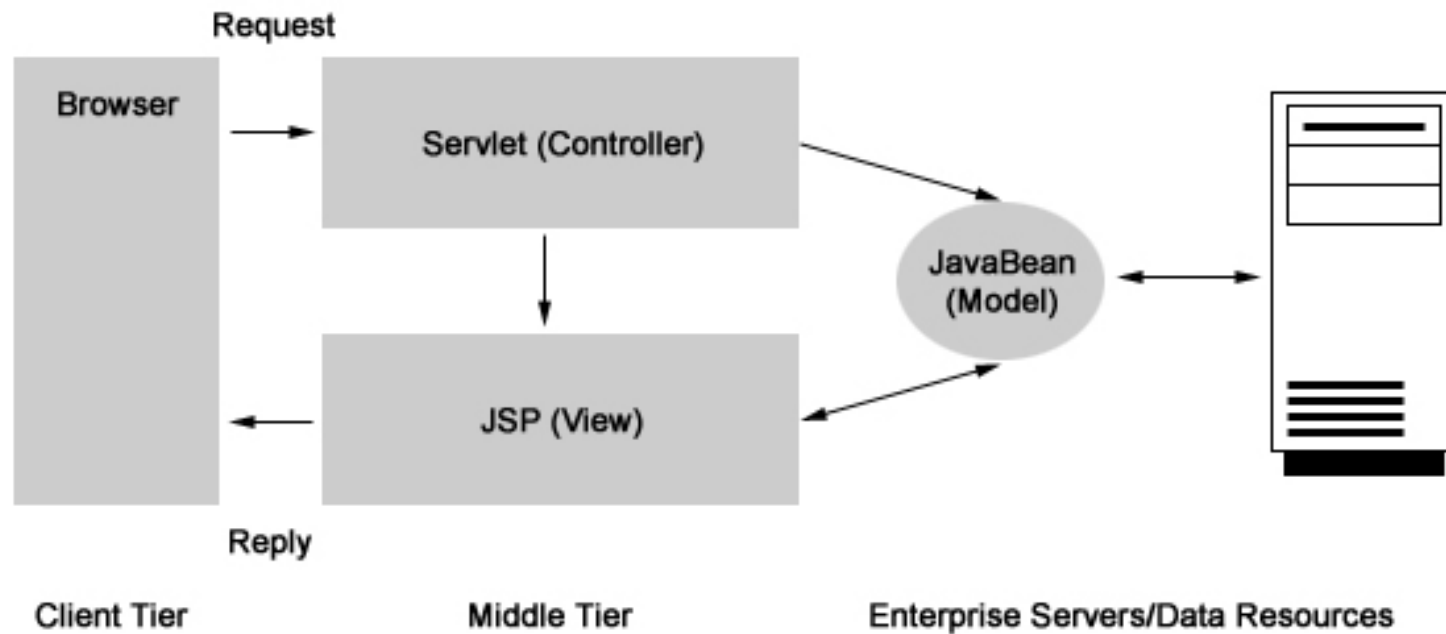


Figure 3
Relation between Model and View.

Researcher Interface

- ◎ View a complete list of research projects in which the researcher is currently working within DSRC.
- ◎ Within each project, view a time line of all associated tasks. These tasks include not only active tasks but also previously completed tasks. Files can be retrieved from previously completed tasks, thus constituting a storage location for all study-related files.
- ◎ Receive instructions for completion of each task, also having the ability to ask questions to research administrators for instructions that have not been clearly given. For each assigned task, researchers can: simply mark a task as completed (for tasks not requiring the submission of a file); download necessary templates and submit them; or fill documents out on an online environment.
- ◎ External to the completion of specific regulatory tasks, researchers also have links for commonly used resources for research such as templates for regulatory documents, information on grant opportunities, and applications that allow for determination of number of patients in the Department of Surgery with a specified combination of diagnostic and procedure codes.

Researcher Interface

Firefox File Edit View Go Bookmarks Tools Window Help
DSRC - Duke Surgery Research Central
https://www.ceso.duke.edu/dsrc/servlet/Controller

Duke Surgery
DUKE UNIVERSITY MEDICAL CENTER

Duke Surgery Research Central
Welcome Mr. Shah **LOGOUT**

RESEARCHER HOME

home resources for researchers message edit user dxpr estimation of num. of patients biosketch ICD search
new project request | view archived projects

Expired task

My Tasks

Task	Project	Deadline
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My Projects

Project Initialize Request

RSI

Principal Investigator/Program Director (Last, First, Middle):
Resident/Fellow (Last, First, Middle Initial):
Project Title (81 characters):

Specific Aims/Research Objective

Done www.ceso.duke.edu

Administrator Interface

- ⦿ Register and update new users with descriptive information such as department affiliation.
- ⦿ Create new projects using information provided by researcher for grants, IRB protocols, and contracts that will be submitted to the research administration office.
- ⦿ Create new tasks within each project, providing individual researchers with instructions, templates, and deadlines for submission of necessary documentation.
- ⦿ Download files submitted by researchers containing the information assigned in their task.
- ⦿ Read and respond to questions submitted by researchers.
- ⦿ Modify project and task information when necessary.
- ⦿ View complete list of projects being processed in the system at any given time, sorted by project name, leader, task, deadline, research administrator name, or researcher name.
- ⦿ In order to ensure that tasks assigned to researchers have been accessed, research administrators have access to a list of researchers who have not accessed the system after seven days since the date of assignment.

Administrator Interface

https://www.ceso.duke.edu - Budget template - Mozilla Firefox

1st Year 2nd Year 3rd Year 4th Year 5th Year Summary Selected: First Year

Principal Investigator/Program Director (Last, First, Middle): Klitzman, Bruce

FROM: (Click on the Calendar) THROUGH: (Click on the Calendar)

DETAILED BUDGET FOR INITIAL BUDGET PERIOD
DIRECT COSTS ONLY

PERSONEL (Application organization only)		TYPE APPT. (months)	% EFFORT ON PROJ.	INST. BASE SALARY	DOLLAR AMOUNT REQUESTED (omit cents)		
NAME	ROLE ON PROJECT				SALARY REQUESTED	FRINGE BENEFITS	TOTALS \$
Bill Smith	PI	12	5	110,739	5,537	1,187	6,724
Tasha Jones	Investigator	12	2	73,425	1,469	315	1,784
TBD	Research Tech	12	25	36,500	9,125	2,259	11,384
							0
							0
							0
							0
							0
							0
							0
							0
							0
							0
				SUBTOTALS	16,131	3,761	19,892

Pro-Rated Benefits -- % (For corresponding rows above)

1st	2nd	3rd	4th	5th	6th	7th	8th	9th	10th	11th
21.43	21.43	24.75								

- Color Key -

- Just for SBO
- Read Only - automatic calculate
- Disabled field
- Field value from last year

CONSULTANT COSTS

Description	Subtotal
	0

EQUIPMENT (Itemize)

Description	Subtotal

Done www.ceso.duke.edu

Done www.ceso.duke.edu

start | http://radio.launch.y... | 6 Firefox | ananduke : maris006 ... | New Memo - Lotus No... | 12:37 PM

Usability

- Formal usability test, plus field survey.
- Formal testing: very little trouble in interface, only 2 users with trouble (computer literacy).
- Field study: bug fixing, quick feedback
 - variable categorization of projects (not free text)--
input & output reliability; search boxes
 - explicit deletion warning mechanisms
 - completion reinforcement

Conclusions

- Challenge of computer literacy
- Incremental software development
- User buy-in (requirements)

Demo