Research Management Review, Volume 18, Number 2
Fall/Winter 2011

Developing an Institution-wide Web-based Research Request and Preliminary Budget Development System

Julia L. Glenn and Royce R. Sampson
Medical University of South Carolina

ABSTRACT

While medical research may often be regarded by academics and the general population in terms of the remarkable science being conducted or the study participants willing to volunteer their time for the advancement of medical innovation, many in the research administration field recognize the tremendous amount of effort that goes on behind the scenes (Shambrook & Roberts, 2011). Accurate budgeting and compliant billing are two of the critical pieces of an evolving research administration puzzle. These activities are vital to the overall success of any research project and to the integrity of the research institution. In today's technology-driven world wherein the term "process improvement" is widespread in academic research, electronic tools to reduce burden and increase efficiency have become a common goal at many research institutions. Along these very lines, the South Carolina Clinical and Translational Research Institute at the Medical University of South Carolina (MUSC), the "academic home" of the National Institutes of Health Clinical and Translational Science Award (UL1RR029882), partnered with the institution's Office of the Associate Provost for Research to develop a streamlined, centralized infrastructure for accurate research budgeting and compliant billing. The purpose of this paper is to describe the conceptual model of an institution-wide secure, web-based research service request and preliminary budget development tool currently under development at the Medical University of South Carolina.

BACKGROUND AND INTRODUCTION

The Medical University of South Carolina (MUSC) was founded in 1824 and today remains the only comprehensive academic health sciences center in the state of South Carolina. The institution strives not only to provide an outstanding educational atmosphere for its students and deliver patient care of the highest quality, but also seeks to be an international leader in the development of new medical knowledge and cutting-edge innovation. To that end, MUSC has a robust portfolio of basic, clinical, and translational research. In FY2010, the institution was awarded more than 1,200 research awards totaling over $234 million and representing over 500 investigators and countless research staff (Office of Research and Sponsored Programs, 2010).

In recent years, MUSC administration and leadership have continuously emphasized the importance of using available technological advances to create streamlined and effective systems for the management, review, and administration of the institution's abundant research. In the last decade, MUSC has implemented electronic tools for the submission and review of Institutional Review Board and Institutional Biosafety Committee applications, grant proposals to the Office of Research and Sponsored Programs, as well as the submission of applications to Grants.gov utilizing a system-to-system interface (Medical University of South Carolina, 2006). While such processes have undergone a technology overhaul, the critical processes of budget development and review as well as compliant research billing have remained static and have been deemed challenging by many research faculty, staff, and administrators. These processes rely almost exclusively on manual paper transactions and constant, repetitive email and face-to-face communications between various contributors to the study, such as the investigator, study coordinators, service providers, and billing specialists. Research study team members must begin to construct their preliminary research budgets by contacting individual service providers separately to obtain pricing for research procedures. For example, price quotes for a myriad of laboratory tests are requested from the individual laboratories performing the tests; quotes for radiological procedures must come from the university's Imaging Center or the Department of Radiology; estimated costs for an entire menu of investigational pharmacological services originate from Investigational Drug Services; quotes for specific research nursing services might be secured from the Clinical and Translational Research Center; and so on. Quotes may be obtained via email, paper applications, or phone calls, depending on the individual service provider. In addition, providers of research-related services often operate in silos. They provide pricing for their specific services,

when in fact protocol procedures are often interrelated. A radiological scan, for example, may require contrast media, the cost for which must be obtained from a different source than the scan itself. The current system requires that the individual requesting research services is: 1) aware of this complicating detail, and 2) obtaining the fee for the scan from the Department of Radiology and the technical (or facility) fee for the administration of the contrast from the Hospital Compliance Billing Office.

Once study teams obtain an "accurate" budget through this current method, the equally complicated coverage analysis process begins. This process also relies heavily on constant communication between research study team members and very specific (and sparse) service providers with valuable but individualized knowledge. Research staff must construct a billing grid complete with every research-related service that may incur a cost and subsequently be billed. The billing grid must indicate whether each identified service will be billed to the study sponsor, is a routine care procedure to be billed to a third party payer (such as the research subject's insurance carrier), or is to be covered by study personnel's effort. Often these grids must be built from scratch. Sponsors of investigator-initiated protocols frequently do not provide a general template complete with all billable study procedures. However, while sponsors of industry-initiated/industry-sponsored protocols often supply such templates, they are extremely different from the way the institution actually bills for services (for example, the common line item of "chemistry" may be comprised of a variety of different billable services). In either case, the study team must generate an original grid. Once the billing grid is complete, a Medicare Coverage Analysis (MCA—a thorough review required for all clinical research studies to ensure that any tests, procedures, and/or interventions performed on study participants and being billed to any third party remain in compliance with legal mandates) must be requested from the University Compliance Office to ensure compliant billing throughout the subsequent study. This review entails manually entering information from the billing grid into a large Excel database so that historical decisions regarding coverage can be accessible at a later date. Coverage decisions are communicated to the study team via email and/or phone. Billing grids and budgets are manually updated as a result of the billing review as needed.

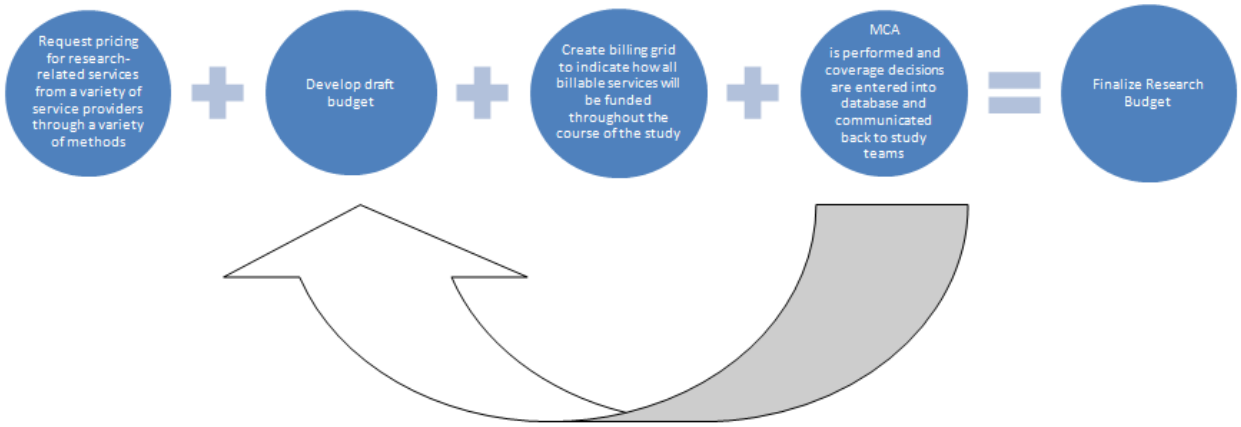


Figure 1. Overview of Research Budgeting and Billing Compliance Review Process at MUSC

This current labor-intensive system of research budgeting and billing compliance review is time-consuming, outdated, and prone to human error. As such, and with a large and growing portfolio of medical research, the South Carolina Clinical and Translational Research Institute (SCTR) and the Office of the Associate Provost for Research sought to develop an electronic system that would accomplish three critical tasks: 1) streamline and centralize the process of requesting research-related services across campus; 2) assist in the timely creation of an accurate preliminary budget and billing grid to ensure research billing compliance for individual research studies; and 3) allow MUSC to be competitive with academic medical centers of similar stature (Stanford University, 2010; Whitney & Wolff, 2011) with regard to electronic research administration and clinical trials management systems. What follows is a discussion of the conceptual model used to develop a comprehensive electronic system for research service requests and budget development at MUSC.

METHODS

Groundwork for the proposed model first began by identifying major stakeholders in the research budgeting and billing process at the MUSC. Key participants, in addition to SCTR and the Office of the Associate Provost for Research, were initially identified as: the Department of Radiology, the Investigational Drug Pharmacy (IDS), University Medical Associates (UMA) and Medical University Hospital Authority (MUHA) Compliance

Billing Offices, the MUHA Clinical Chemistry Laboratory (MUHA Lab), and the Department of Medicine. These stakeholders were approached with the basic concept of a centralized electronic research request and preliminary budgeting infrastructure and asked to lend support to the project by endorsing the pilot-testing of the proposed system for day-to-day research service requests and approvals. Early meetings with the stakeholders centered on functionality of the proposed system and changes to current workflow. After their endorsement, key project personnel were identified (see Table 1).

These personnel set three goals at the outset of the conceptual model development. With the help and expertise of identified stakeholders, SCTR research specialists, SCTR biomedical informatics programmers and analysts, and departmental research administration professionals who can offer proficient pilot-testing and recommendations, project personnel sought to:

- develop a dynamic and intuitive user interface prototype wherein faculty and staff can request research services from multiple service providers simultaneously and concurrently develop associated research service-related budgets and billing grids with ease;
- develop a streamlined administrative portal model wherein service providers can electronically manage, review, and approve requests for research services and prices as well as provide a thorough billing compliance review; and
- keep all identified stakeholders engaged and informed throughout development to encourage their ongoing recommendations and continued support for the project.

RESULTS

Goal 1. Develop a User Interface Prototype

Project personnel identified three basic objectives for the original user interface model: a) allow users to request research services and associated pricing from various service providers simultaneously via an electronic system; b) allow users to construct a preliminary billing grid and subsequent draft research budget using the requested research services and prices electronically; and c) allow users to electronically indicate how requested research services will be billed/funded for billing compliance review.

To achieve the first objective, project personnel, in collaboration with the service providers whose research services would ultimately be displayed in the system, developed the service catalog interface displayed in Figure 2.

Table 1. Key Project Personnel and Project Roles

Project Title	Project Personnel & Affiliations	Project Role
Project Owner	Royce Sampson, MSN, RN, CRA *SCTR SUCCESS Center*	• Overall concept development • Map out system functionality • Strategic planning for phased system rollout • Review and approve all system content and design • Obtain project funding and SCTR Leadership approval
Project Leader (2)	Lane Glenn, BS, MRA *SCTR SUCCESS Center* Amanda Zimmerman, BA *SCTR SUCCESS Center*	• Assist Project Owner with overall concept development • Assist Project Owner with outlining system functionality • Develop system content and design (user interface and administrative portal) for Project Owner approval • Work with stakeholders to identify system need and requirements • Collaborated with SCTR Office of Biomedical Informatics during system development on problems encountered to offer solutions and additional system options
Lead Developer	Mark Gunnels, BA *SCTR Office of Biomedical Informatics*	• Analyzes the Project Owner's/Leaders' scope of work regarding system functionality and design and creates appropriate system programming solutions • Responsible for the overall architectural design of the system from a programming and software perspective
Infrastructure Lead	John Clark *SCTR Office of Biomedical Informatics*	• Responsible for the implementation of the system from a hardware and networking perspective
Lead Collaborator	Loretta Lynch-Reichert, MS *Office of the Associate Provost for Research*	• Works with key institutional stakeholders to achieve buy-in on and support for the proposed system
Project Manager	Maynard Cain, BS, MBA, PMP *SCTR Office of Biomedical Informatics*	• Maps out SCTR biomedical informatics staff tasks and timelines in accordance with Project Owner's/Leaders' plan to ensure timely completion of the project
Project Programmer (4)	Andrew Cates (Lead), BS *SCTR Office of Biomedical Informatics* Jed Schneider, BS, MA *SCTR Office of Biomedical Informatics* Gary Fredericks, BS, MBA *SCTR Office of Biomedical Informatics* Matthew Scott, BA *SCTR Office of Biomedical Informatics*	• Manages biomedical informatics development process • Implements actual system content and design from a programming perspective • Responsible for performing daily/weekly development tasks in support of system release • Provides general system maintenance

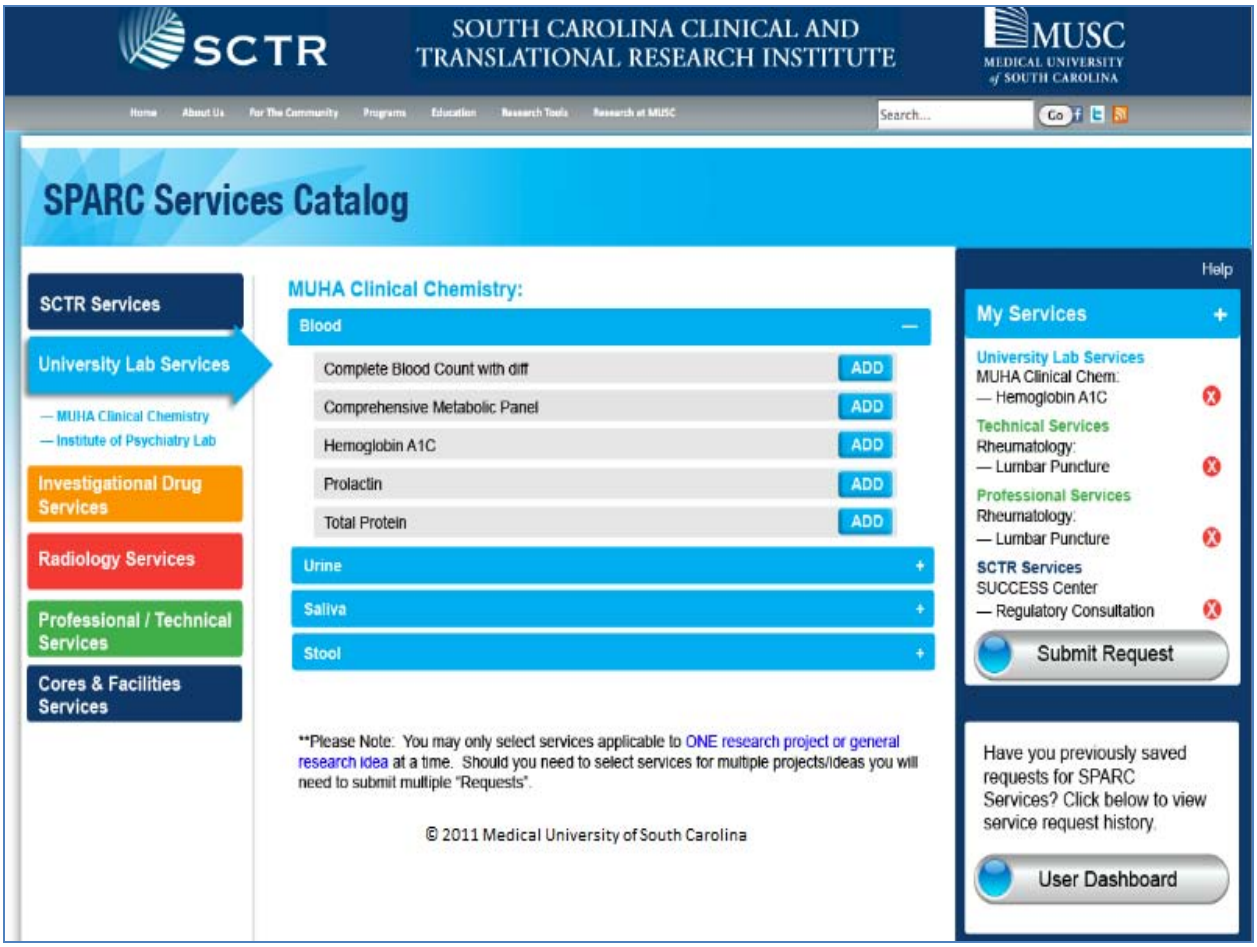


Figure 2. Electronic Service Catalog Prototype

Using online shopping as a model, project personnel created a prototype wherein users can easily search for research services under logical groupings. Much like shoppers can search for genres of books at online bookstores, users can search for groupings of various services, such as Laboratory, Radiology, Investigational Drug, etc., or perform a simple search for one particular service. Users can browse services under any of the listed service providers. As users find the service they are looking for, they simply click "ADD" to include the service in "My Services," which is analogous with an online shopping cart. Rather than requesting services from each service provider separately, users can now select services from multiple providers concurrently.

The system allows each request to be associated with one research project. Users may associate the newly submitted service request to a project that already exists in the system or enter a new project (Figure 3) by providing some basic project information such as title, involvement of human subjects

and/or research animals, and funding source, as well as authorize project personnel for system access and specific rights. Next, users are asked to provide the estimated total number of subjects and estimated total number of visits to begin constructing their preliminary budget (Figure 4).

With this initial information, the system generates an electronic billing grid template. To achieve their second and third objectives, project personnel created a billing grid with multifunctional views—allowing users to accomplish two tasks: 1) generate an initial budget based on the research services requested, the quantity of selected services at each visit, and the current fees from each of the appropriate service providers, and 2) indicate how each requested service will be billed throughout the course of the study for a thorough billing compliance review. As illustrated in Figure 5, users first enter the number of times per visit that each service is to be completed (1st grid), followed by the funding source (2nd grid). A preliminary research budget (3rd grid) is then produced. Fees that are to be billed to a third party or are to be covered by study personnel's effort are not included in this original budget.

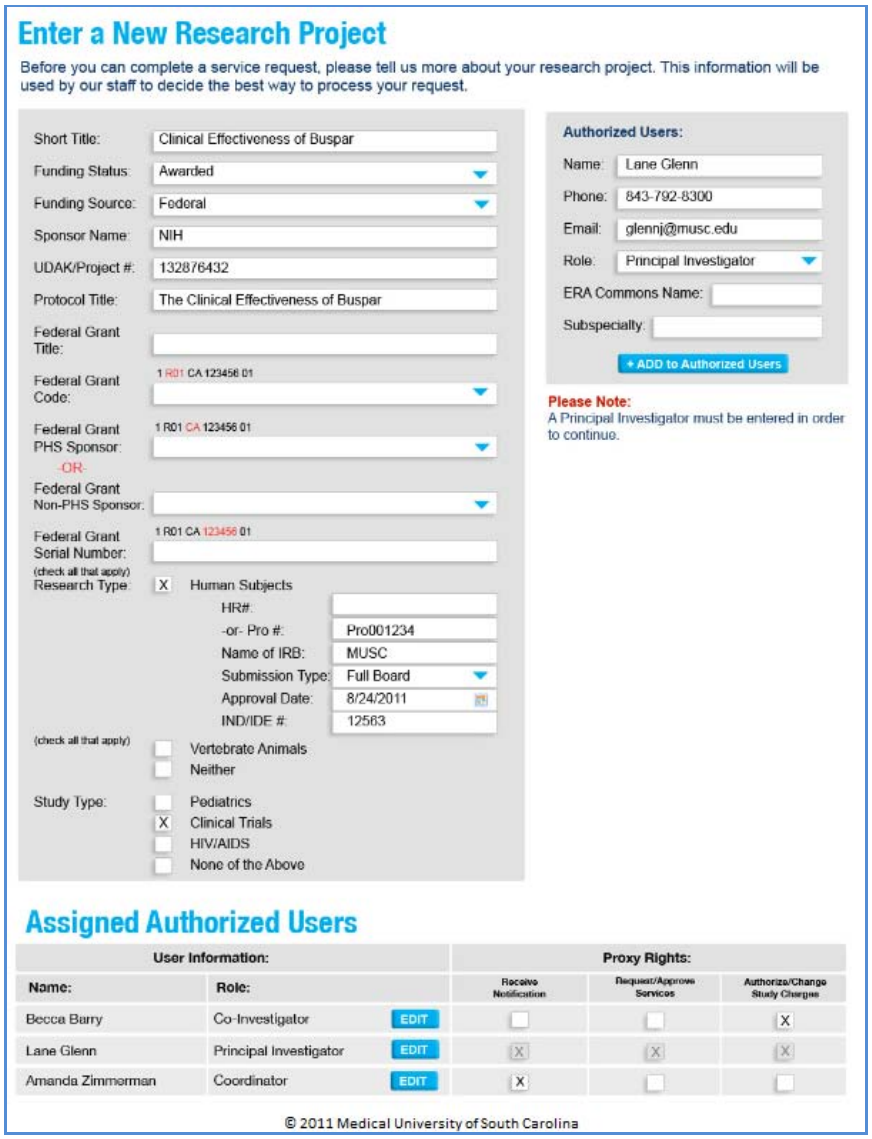


Figure 3. New Research Project Prototype

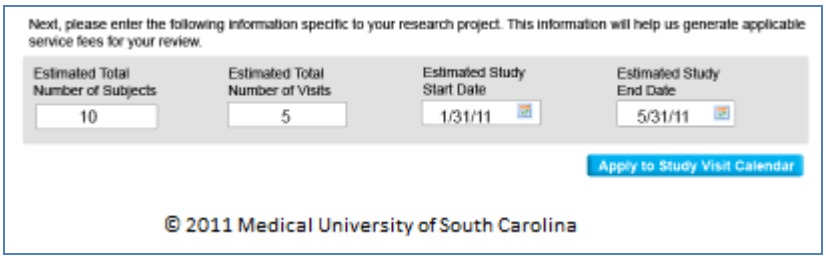
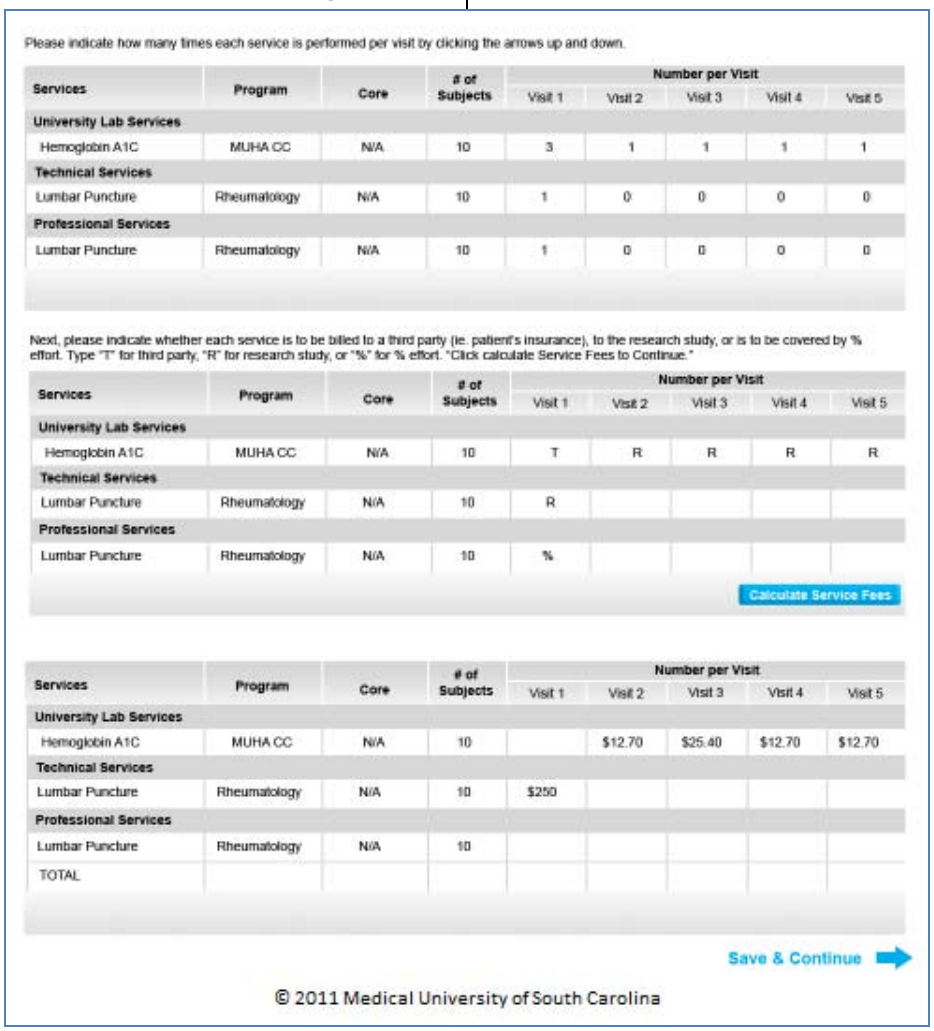


Figure 4. Preliminary Budget Information Prototype

With this initial information, the system generates an electronic billing grid template. To achieve their second and third objectives, project personnel created a billing grid with multifunctional views—allowing users to accomplish two tasks: 1) generate an initial budget based on the research services requested, the quantity of selected services at each visit, and the current fees from each of the appropriate service providers, and 2) indicate how each requested service will be billed throughout the course of the study for a thorough billing compliance review. As illustrated in Figure 5, users first enter the number of times per visit that each service is to be completed (1st grid), followed by the funding source (2nd grid). A preliminary research budget (3rd grid) is then produced. Fees that are to be billed to a third party or are to be covered by study personnel's effort are not included in this original budget.


Please indicate how many times each service is performed per visit by clicking the arrows up and down.

Services	Program	Core	# of Subjects	Number per Visit				
				Visit 1	Visit 2	Visit 3	Visit 4	Visit 5
University Lab Services								
Hemoglobin A1C	MUHA CC	N/A	10	3	1	1	1	1
Technical Services								
Lumbar Puncture	Rheumatology	N/A	10	1	0	0	0	0
Professional Services								
Lumbar Puncture	Rheumatology	N/A	10	1	0	0	0	0

Next, please indicate whether each service is to be billed to a third party (ie. patient's insurance), to the research study, or is to be covered by % effort. Type "T" for third party, "R" for research study, or "%" for % effort. "Click calculate Service Fees to Continue."

Services	Program	Core	# of Subjects	Number per Visit				
				Visit 1	Visit 2	Visit 3	Visit 4	Visit 5
University Lab Services								
Hemoglobin A1C	MUHA CC	N/A	10	T	R	R	R	R
Technical Services								
Lumbar Puncture	Rheumatology	N/A	10	R				
Professional Services								
Lumbar Puncture	Rheumatology	N/A	10	%				

Calculate Service Fees

Services	Program	Core	# of Subjects	Number per Visit				
				Visit 1	Visit 2	Visit 3	Visit 4	Visit 5
University Lab Services								
Hemoglobin A1C	MUHA CC	N/A	10		$12.70	$25.40	$12.70	$12.70
Technical Services								
Lumbar Puncture	Rheumatology	N/A	10	$250				
Professional Services								
Lumbar Puncture	Rheumatology	N/A	10					
TOTAL								

Save & Continue

Figure 5. Preliminary Billing Grid/Research Budget Prototype

Goal 2. Develop an Administrative Portal Prototype

A robust and intuitive administrative portal is as important as the user interface to ensure success of the system as well as stakeholder buy-in. The administrative portal allows system administrators to manage, review, and approve users' service requests within a centralized electronic portal. Project personnel identified three key objectives for the proposed administrative prototype: a) allow administrators to receive service requests electronically and quickly view all service requests for their program by status; b) allow administrators to review services of individual requests for approval and tracking purposes; and c) allow administrators to view services requested from other programs to help identify additional required services (for example, contrast media for a particular radiological exam) as needed.

To achieve the first objective a familiar, email-type interface was adopted, wherein administrators can view all service requests for their program sorted by status (Figure 6).

Figure 6. Administrative Portal "Inbox"

Similar to any modern email client, administrators have an "Inbox" ("Submitted Requests") where newly submitted requests that need to be addressed reside until the Administrator changes the status from "Submitted" to "In Process." Once logged in, the administrative portal automatically defaults to this "Inbox" view. The folders indicating status ("Submitted," "In Process," "Completed")

denote the phase of service request review. Administrators can quickly move back and forth between each status to gauge workflow and any outstanding issues at a glance. Administrators can likewise place requests "On Hold" (for example, if the sponsor of a study has put the study on clinical hold for further FDA review), which removes the request from the standard service request status folders and places it in the "On Hold" folder until manually changed by the administrator. Administrators can likewise send requests out for additional "PI Review" prior to approval (if the contents of the request have changed dramatically from initial submission, for example). Changing a request to "PI Review" status generates an automatic email from the system to the principal investigator summarizing request changes that require his/her approval. Similarly, when any request has been reviewed and approved (described below), the system places the request in the "Completed" tab. This folder (status) view provides a global, multiple-project perspective that facilitates efficient administrative management of the service requests for the program. Within each folder, each request also includes an abbreviated view of pertinent request information: the names of the principal investigator and requester as well as an overview of services being requested (available in a drop-down menu). Additional features of the administrative portal include the ability to assign any request to a particular staff member for management, review, and approval and to access individual service request details by clicking on the hyperlinked Service Request Identification Number, SRID.

Administrators have a variety of tools available to them in the Service Request Details module (Figure 7).

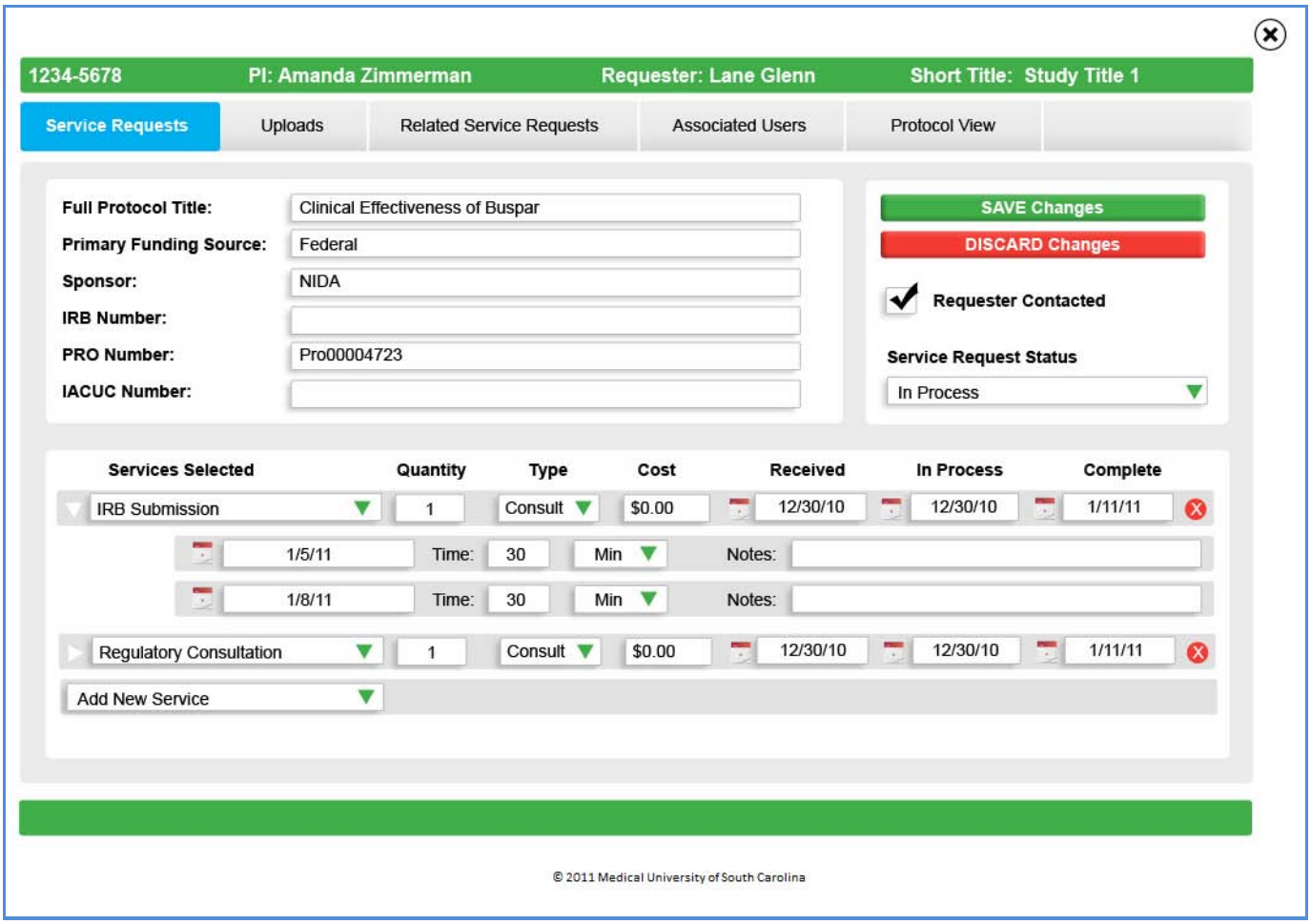


Figure 7. Administrative Portal—Service Request Details Prototype

To accomplish the second and third objectives for the Administrative Portal, project personnel designed a multipurpose Service Request Details module wherein administrators can view both in-depth details about the protocol itself (funding source, sponsor, IRB and IACUC numbers, etc.) as well as the individual services being requested. Within this module, administrators can review, edit, and/or complete data required for service request processing, tracking, and reporting. Examples include ensuring that users have requested the correct services, entered the correct quantity, and received the appropriate service pricing (the system accommodates multiple-tiered pricing dependent upon funding source). Administrators can add and/or delete services to the request as indicated through review of project and/or after discussing the request with the requester and investigator. Since many institutional service providers have policies that require requesters to be

contacted within 24 hours of the initial request, the system also tracks the date and time of status change for comparison with established program metrics for evaluation and reporting as well as for continued process improvement activities.

In addition, administrators not only have access to any pertinent documents users may have attached to the initial request under the "Uploads" tab but can also upload applicable documents related to the service request to facilitate the proposal pricing process, document work fulfillment, or share pertinent information directly with the investigative team (Figure 8). Often, review of a protocol and consent by the service provider helps to ensure that all necessary services have been requested and pricing is accurate. Likewise, this ability for users and administrators to share documents can facilitate effective service consults as needed in areas such as regulatory, ethics, and biostatistics. All service request documents are accessible to the requester, the Principal Investigator, and any other users given access. This feature allows service providers and users to "communicate" as needed through a versioned/auditable document repository.

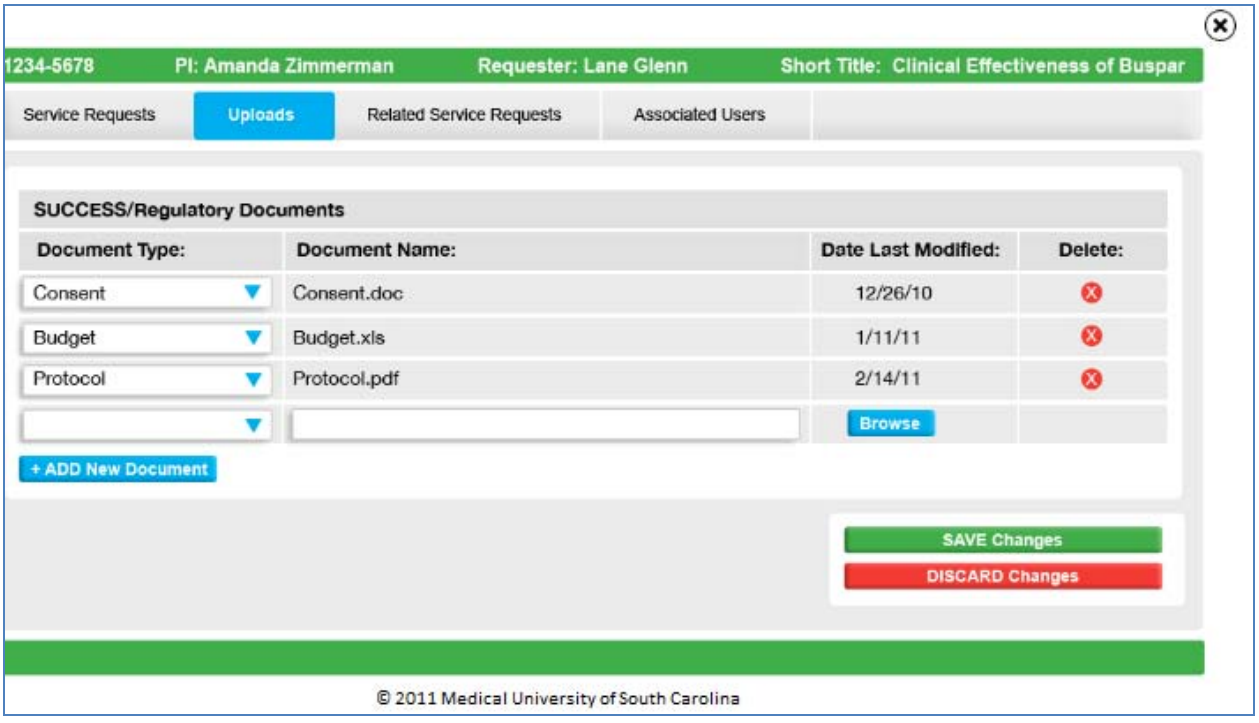


Figure 8. Administrative Portal—Document Repository Prototype

Lastly, to view those services requested from other programs for any individual service request, administrators simply click on the "Related Service Requests" tab within the module (Figure 9). Like their Administrator Inbox, administrators have access to an abbreviated view of all other service providers involved in the protocol as well as individual services requested from each provider. This functionality ensures that service providers do not operate in silos but are able to provide integrated, collaborative, and comprehensive services in order to better promote the success and compliance of investigators' requests.

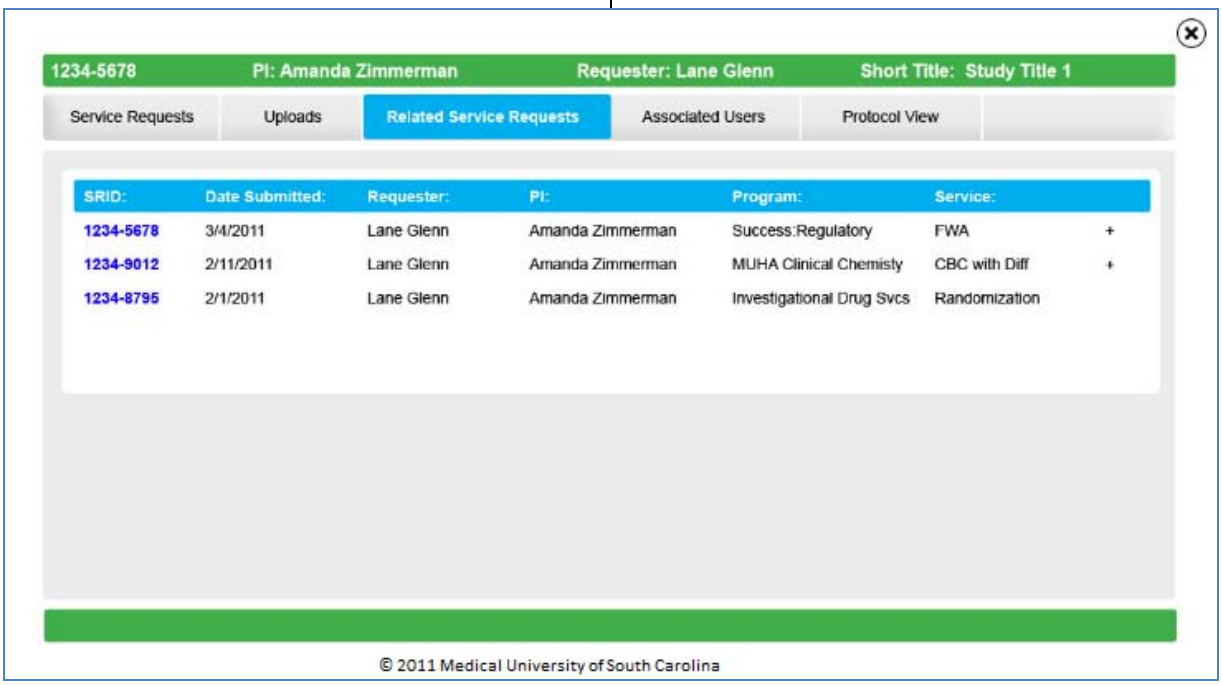


Figure 9. Administrative Portal—Associated Service Requests Prototype

Goal 3. Engaging and Informing Stakeholders

Due to the trans-institutional nature of this project, as well as multiple and diverse service providers and potential system users, project personnel recognized the critical importance of keeping all stakeholders engaged, involved, and informed throughout conceptual model development. Encouraging input, suggestions, and pilot testing from stakeholders would be the key to the overall success and eventual institutional adoption of the model. To succeed, this system could not simply be the sole innovation of SCTR.

To achieve this crucial goal, project personnel employed a variety of methods, including bi-monthly meetings with all identified service providers. With all providers convened together in an open forum, suggestions for and concerns with the proposed system were elicited and

encouraged. Because providers had a long history of operating separately, this joint meeting proved extremely beneficial. Providers were able to discern how others operated and discuss centralized workflow through the new system. Project personnel were able to identify additional features that may allow the system to function even more efficiently. Project personnel also arranged separate meetings with individual service providers to ensure that no one provider perceived any major difficulties or issues with the system, as well as to encourage providers to voice ideas on how to enhance the system using their individualized knowledge.

To keep potential system users engaged and informed during conceptual model development, project personnel also participated in a number of bi-monthly campus outreach meetings (departmental meetings, clinical trials billing meetings, Lunch 'n' Learn presentations). During each meeting, project personnel gave a brief overview of the proposed system (functionality, use cases, proposed workflow) as well as an update on the conceptual model development and future implementation. User feedback, small user workgroup participation, and user pilot testers were solicited during each meeting.

To garner support from institutional leadership and administration, project personnel provided a number of brief presentations on the proposed system at the College of Medicine Dean's Council meeting as well as various Departmental Administrators meetings. All presentations were received enthusiastically.

The success of these assorted techniques to keep stakeholders engaged and informed has been evaluated by several metrics. The number of service providers wishing to partake in the system has grown from the original six to more than 10, and the list continues to grow with the recent addition of numerous institutional Cores and Facilities. Project personnel have identified no fewer than 15 departments and divisions across campus requesting to utilize the system for requesting and budgeting for services, ranging from Transplant Surgery, to Pediatric Cardiology, to Radiology.

Conclusion and Next Steps

These results, which demonstrate the successful development of comprehensive prototypes that delineate a practical and efficient means of electronically managing, reviewing, and administering a variety of vital pre-award activities, while ensuring the continued interest and participation of current stakeholders and encouraging future participants, have clear implications for the proposed system.

Due to such sizeable interest in the proposal from not only the individual providers of research-related services but also from the research administration community at large, development of the system has begun in earnest. The SCTR Biomedical Informatics Program has

dedicated five full-time programmers and analysts to the project in hopes of releasing the first iteration of the system in late Fall 2011. In preparation for this release, project leaders and project managers continue to publicize the conceptual model of the system across campus—to individual departments and divisions, research administrators, and top institutional leaders—in order to garner further support and solicit additional feedback for future upgrades and enhancements. In addition, project personnel have begun to draft a training and education plan to coincide with the release. System training will focus on both broad institutional education (Tegrity sessions available to all users, SCTR Lunch 'n' Learn presentations, new faculty orientation, etc.) and individualized/one-on-one training sessions as requested.

Proposals for future system enhancements and upgrades already abound. Planning and designing activities have already begun to incorporate the first of many such system augmentations. After the release of the initial system this fall, SCTR and its collaborators will begin to develop a robust user dashboard (a prototype of which is displayed below) that will display an overview of pertinent study and investigator information, such as a list of all protocols and service requests within the system, a catalog of related grants and publications, system notifications, etc.

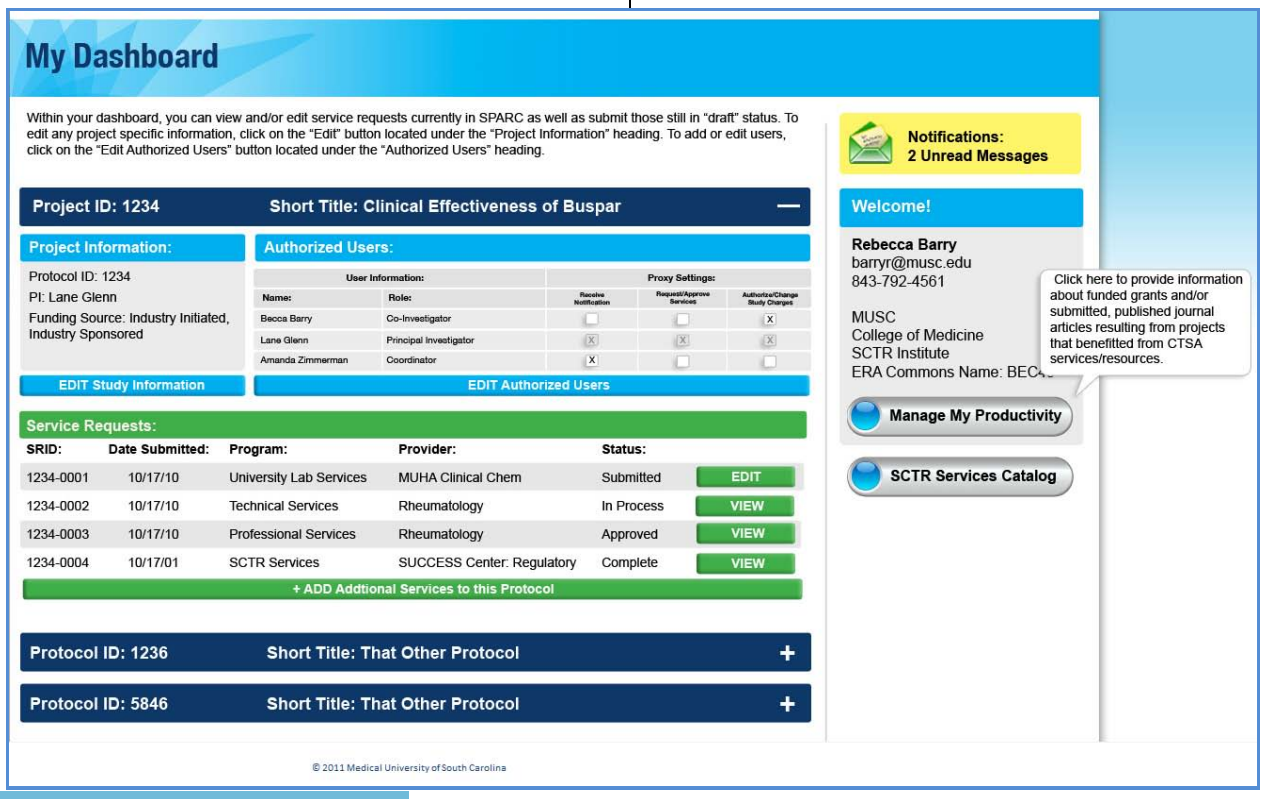


Figure 10. User Dashboard

In addition, SCTR will begin to develop a strong study tracking and work fulfillment infrastructure that ties directly into the request and budget development system. This study tracking system (a small pilot of which has already been released for early feedback) is multifunctional and will enable study team members to track work performed on a discrete study (at the individual study participant and visit level) for sponsor invoicing purposes and service providers to track work performed within their individual service centers for PI billing.

Other proposed upgrades that will be explored include: an electronic subject enrollment log and visit scheduling calendar, a consent tracking and versioning system, and electronic source documentation abilities.

ACKNOWLEDGMENTS

The authors thank Amanda Zimmerman for her wonderful graphic design and the SCTR Office of Biomedical Informatics System for its tremendous development abilities, without which this project would have been nearly impossible. Furthermore, the authors wish to thank the continued support and superb ideas of Loretta Lynch-Reichert, Stephen Skelton, Stephanie Gentilin, Randal Davis, Rebecca Barry, Reece Smith, Susan Rittman, Romeka Washington, Kimberly Porter, Dixie McMahan, Faleshia Davis, and Patti Lofmark.

AUTHORS' NOTE

The project described was supported by Grant No. UL1RR029882 from the National Center for Research Resources. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Center for Research Resources or the National Institutes of Health.

LITERATURE CITED

Annual report of grant and contract activity (Annual Research Report 2010). (2010). Retrieved from Office of Research and Sponsored Programs website: http://research.musc.edu/orsp/Reports/FY10.pdf

Applications go electronic; MUSC is ready. (2006). Retrieved June 11, 2011, from Medical University of South Carolina website: http://www.musc.edu/catalyst/archive/2006/co12-15applications.html

Gaich, N. (2010). *Stanford's "Epic" implementation journey: Integration of clinical and research requirements.* PowerPoint presented at CTSA Clinical Research Management Workshop. Bethesda, MD.

Shambrook, J., & Roberts, T. J. (2011). 2010 profile of a research administrator. *Research Management Review*, *18*(1), 1–12.

Whitney, G., & Wolff, J. (2011). *Integrating clinical trials management and billing with Epic* [PowerPoint Presentation]. Retrieved from https://www.clickcommerce.com/cc/resource/DOC00032857