eProtocol is a research compliance management system to support the administration of research involving human or animal subjects to ensure ethical standards and meet regulatory requirements. These areas are overseen by separate campus compliance committees -- the Institutional Review Board (IRB) for human subjects, and the Institutional Animal Care & Use Committee (IACUC) for animal subjects, and each area has its own compliance requirements and operational procedures. The administrative structures that support these committees, as well as the Conflict of Interest Committee (CoI) and the Sponsored Projects Office (SPO), report to the Assistant Vice Chancellor for Research, an organizational structure that demonstrates the close ties between these functions.

eProtocol is a web-based protocol management system that automates IRB/IACUC workflow and operations, including management of review committees, and electronic protocol preparation, submission, routing, review, tracking, approval, and closeout. It is also designed to integrate closely with contract and grant systems supporting SPO and CoI functions (i.e. the Coeus contract & grant system, currently undergoing an extensive upgrade that includes eProtocol integration). It enables researchers, IRB/IACUC panelists and staff, and research managers to develop, access, and process protocol applications online. The eProtocol system will support our world-renowned research program by facilitating compliance, enhancing protections for human and animal subjects of research, saving valuable time for researchers and staff, and providing critical data to support strategic management decisions.

1. Alignment with IT Strategic Plan

This project is directly responsive to the IT Strategic Plan -- Critical Issue 3, Research, Priority 1, Basic IT Resources. Researchers and staff across disciplines require the use of common and integrated systems to support interdisciplinary, collaborative research. The lack of common administrative systems to support research slows research and wastes precious researcher time and research dollars on rework and retraining.

2. Impact

The eProtocol project affects researchers and staff campus-wide and may eventually extend to LBNL in support of IRB transactions. In the last year our IRB reviewed nearly 1500 new and amended protocols and the IACUC reviewed close to 300 new and revised protocols submitted by hundreds of faculty, students and staff. These
projects represent millions of dollars in research funds with significant compliance requirements.

3. Risk assessment

The regulatory requirements that are designed to protect human and animals subjects in research are extremely complex, deeply intertwined with other research administration functions, and strictly monitored by federal, state and other agencies. Noncompliance at other world-class research universities has led to serious sanctions up to and including total shut-downs of university-wide research programs. With more than $500 million in annual research funding at Berkeley, noncompliance increases the potential for adverse consequences to human and animal subjects of research, and jeopardizes the work of hundreds of faculty, students and staff.

A research program of this size makes it impossible to manage compliance requirements by hand. For example, the Sponsored Projects Office cannot release a grant award for research to begin or continue unless all required protocol approvals have been obtained. Without closely integrated systems, the processes for confirming compliance are excessively manual and paper-based, leading to delays for researchers, lapses in compliance and greatly increased institutional risk.

There are risks in undertaking this project as well. System implementation will call for significant changes in work processes on campus and in the central RAC offices. We will need broad buy-in from faculty, management and staff. System integrations points may be difficult. However, a plan that relies on ongoing maintenance of manual compliance management systems is more risky. With our integrated organizational structure, experienced team, careful planning, and appropriate resources, we will have successful implementation.

4. Innovation

Implementation of eProtocol will transform a burdensome paper-based process into a user-friendly online system with built-in tracking, reminders, administrative and operational functions, and reporting capabilities. eProtocol will provide a common user interface for researchers working with the campus IRB and IACUC, and will ultimately integrate with all central research systems to facilitate regulatory compliance and streamline research administration business processes.

5. Funding model

The current funding request is part of the multi-year program outlined on the attached spreadsheet. Funding is based on collaboration between the Vice Chancellor for Research, RAC and IS&T. Extensive use of campus IT infrastructure (database, web, backup, and storage services) is a key component of this project, as is leveraging the use of those resources with those already in place for the ongoing Coeus Upgrade project.
The consequences of not funding this activity are simple and severe. Literally, Berkeley’s entire research program could be shut down, and the University’s reputation severely damaged, by a lapse in regulatory compliance. The impact on future contract and grant revenue for the campus would be significant. Further, the campus will continue to waste precious faculty, student, and staff time and effort working with onerous and antiquated paper-driven systems for protocol management.

The eProtocol system is a critical component of realizing the goal of providing a centralized set of integrated online tools for comprehensive research management at UC Berkeley.