



Integrated Protocol Management Software Solutions for IRB Human Subjects

What we do

Study complex processes and convert them to a comprehensive yet easy-to-use web-based applications to strengthen the Human / Animal Subjects clinical research environment and enhance the protection of subjects to meet the ethical standards and the regulatory requirements.

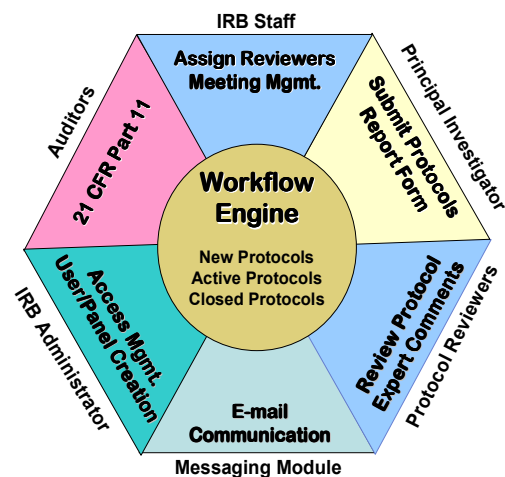
Key Highlights and Benefits

- **Web-based Online System** — does not require any expensive software on your PC and you don't worry if you have the current updates, just need a browser.
- **Automatic Check for Completeness** — so you don't have to spend a lot of time reviewing to determine if all the data is there before submission.
- **Paperless Review** — is an enormous time saver and ensures all documents are easily available from one source.
- **Workflow-based messaging** — alerts members of needed attention to a protocol ensuring its timely action.
- **Version Control** — drastically reduces the time to search and display side-by-side changes.
- **Adverse Events** — reports can easily be generated online with the protocol.
- **Audit Trail** — provides the ability to rapidly locate when and what was done in the protocol.
- **21 CFR Part 11 Compliance** — meets recommended guidelines for managing and protecting electronic records and signatures.
- **Consent Form Builder** — provide for quick creating of new or modifying existing consent forms to conform to your institution and regulations.

eProtocol Software System for IRB

Principal investigators, managers and reviewers know how exacting, time-consuming and daunting the submission of protocols for review can be. It is the foundation of any trial or study, and needs to be done with ethical care, skillfully, yet within a reasonable amount of time. Managers are often handling dozens of projects resulting in increased pressures to meet deadlines. eProtocol simplifies the protocol creation, review and approval process of any number of protocols and saves valuable time in getting a study started.

Architecture: Based on the principles of modularity the flexible architecture of eProtocol allows for simple use and management of the system, without the need for extensive training.



Overview

Online protocol submission: With a browser you can log into the eProtocol system.

- Stay current on the status of all protocols
- No need to acquire reports from other locations
- Receive email notifications of feedback comments on a protocol that require your attention

Protocol Review and Meeting Management:

- See who has reviewed which protocol and status
- View comments and feedback from reviewer through IRB manager to the Investigator.
- Set up and build agendas for meetings with panel members
- Record minutes during the meeting with meeting-minutes builders

Reports: Many routine reports as well as generic reports can be created and generated

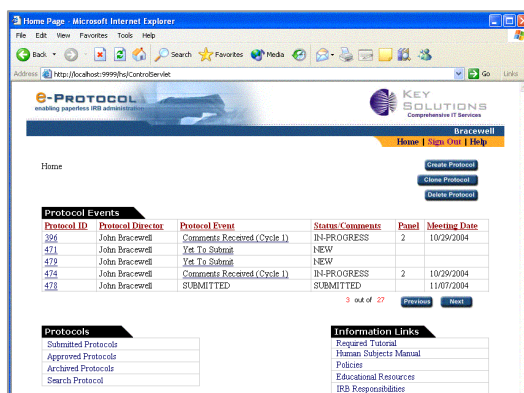
- Available formats include PDF, HTML or Excel formats
- Encrypted signatures for use with Approval Letters and other documents

Workflow-based messaging:

- Alert email messages sent to members of the review team advising of needed attention to a protocol. Email channels between Investigator, IRB and Reviewers.

Program Management:

- Panel and User creation
- Create standard text
- Archival of closed protocols that can later be cloned or revised



Options and Services

Pricing Options: offers a choice of securing the web-based application at **your site** under a **one-time license**, **monthly license payment plan** or a low cost monthly **ASP** option where **we host** the application and manage all the hardware and provide the IT staff needed.

Integration Services: are available to link other mission critical systems to eProtocol such as **Grants, Trial/Study tracking** or **accounting**.

Hosting Services: are available to host the licensed eProtocol application **at our site** for a quoted monthly fee. This frees your institution from all IT hardware and support staffing issues and added expense.

Help Desk Support: provides phone and email support for eProtocol application end-users.

IT Application Maintenance: **onsite** or **remote maintenance** for eProtocol application to keep your system at peak efficiency.

Why Key Solutions, Inc.

Key Solutions has been a pioneer of specialty field applications since founded in 1991 in Santa Clara, California. The company gained a reputation for innovative and reliable IT custom services. Over the past six years Key Solution's focus has been in health care and life science applications that are richly comprehensive, customizable, scalable, and web-based.



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