

# WEB-BASED EDUCATION AND TRAINING

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**Abstract:** *Kaiser Permanente, Southern California uses Web-based education and training to improve investigator knowledge and compliance. This article highlights the organization's participation in the Collaborative IRB Training Initiative, a Web-based tutorial and testing site that is continually updated to reflect changes in human subject law and regulation. The Collaborative IRB Training Initiative consists of 13 core units and an option for an additional institution-specific module and quiz. More than 92 institutions currently participate. The program's advantages, which include user friendly program management; 24/7 access; cost effectiveness; CME credits; a printable certification of completion; and institutional reports, are described.*

Founded in 1945, Kaiser Permanente is the nation's largest non-profit health plan serving 8.5 million members in California, Colorado, Georgia, Hawaii, Maryland, Ohio, Oregon, Virginia, and Washington, DC. Kaiser Permanente has 29 medical centers, 423 medical offices, 90,000 employees, 12,000 physicians, and 8 independent institutional review boards (IRBs). Each IRB reviews research conducted within its region. Many people have been members of Kaiser Permanente for more than 20 years. HMOs such as Kaiser Permanente are a good resource for conducting research because they provide medical services to many members inside a closed healthcare system with combined institutional records (e.g., laboratory, pharmacy, cost, and primary care information). The particulars of this article are limited to Kaiser Permanente in Southern California.

## **Education and Training Programs at Kaiser Permanente, Southern California**

The Department of Research and Evaluation has used seminars and discussion groups, a local education requirement, and Web-based training to improve compliance at Kaiser Permanente, Southern California. In October 2000, the requirement that all federally-funded studies have an educational component documented in the grant proposal went into effect. In November 2000, Kaiser Permanente, Southern California decided that all investigators and IRB members should complete the University of Rochester manual and obtain a certificate of completion. This was required for all research studies, regardless of the funding source. In January 2001, an e-mail announcement was sent to all investigators explaining that documentation of human subject education would be required by

April 15, 2001. In March 2001, an e-mail reminder about the deadline was also circulated.

Kaiser Permanente, Southern California uses different types of educational programs to capture different research groups. People are trained according to regions/committees, location, and specialty. Regions/committees, for example, include the accreditation and licensing committee, the data acquisition team, the regional bioethics committee, the regional cancer committee, residency program directors, and the technology assessment guidelines unit. Examples of training by location and specialty include Los Angeles Medical Center (cardiology and infectious diseases) and San Diego Medical Center (allergy and gastroenterology). Categorization by specialty also includes, for example, laboratory managers, the orthopedic study

group/journal club, the division of surgical oncology, the department of urology, and transplant services. Sometimes the Department facilitates a video conference, for example, with three separate medical centers in Orange County. Kaiser Permanente, Southern California also offers comprehensive consulting services on an individual basis.

The Department of Research and Evaluation Web site is located on Kaiser Permanente, Southern California's intranet and contains information on the following IRB-related topics:

- Department overview and services
- Policies and procedures
- Contact information
- Application and forms
- Consent form checklist
- Funding sources and information
- Annual reports

**The Collaborative IRB Training Initiative**

In January 2002, Kaiser Permanente, Southern California began participating in the nationwide Collaborative IRB Training Initiative, a Web-based tutorial and testing site that is continually updated to reflect changes in human subject law and regulation. Kaiser Permanente, Southern California now uses this program instead of the University of Rochester manual. IRB professionals from around the country developed the Collaborative IRB Training Initiative course. It contains 13 separate units and features an option for an institution-specific module and quiz. About 92 institutions of different types and sizes (e.g., academic, non-academic, federal, private, and pharmaceutical companies) participate in the Collaborative IRB Training Initiative. Effective April 1, 2002, Kaiser Permanente,

Southern California accepts only Collaborative IRB Training Initiative certifications.

Table 1 outlines the Collaborative IRB Training Initiative course content. The course begins with a background section on the history and ethics behind the development of human subject research protections. The course has sections on the regulations, the process of informed consent, social and behavioral research, record-based research and chart reviews, and genetic research. The section on research with vulnerable subjects covers prisoners, pregnant

women, minors, and cognitively impaired subjects. There are sections on community consultation for institutions that enroll Native American subjects, and a section on research with INDs, IDEs, and biologics. There are also sections specific to human subjects research and human research protections at Veterans Administration facilities, and on the International Conference on Harmonization. The section on hot topics evolves continually while the overall course curriculum is updated at least once each year. All participating institutions have the option to develop an institutional page with a quiz at the end of the course.

<b>Table 1 The Collaborative IRB Training Initiative Course Content</b>
<ul style="list-style-type: none"> <li>• History and ethical principles</li> <li>• Regulations and process</li> <li>• Informed consent</li> <li>• Social/behavioral research</li> <li>• Records-based research</li> <li>• Genetics research</li> <li>• Research with vulnerable subjects</li> <li>• Community consultation and IRB review</li> <li>• Research with INDs, IDEs, and biologics</li> <li>• Human subjects research at Veterans Administration facilities</li> <li>• The International Conference on Harmonization</li> <li>• Research protection in the Department of Veterans Administration</li> <li>• Hot topics</li> <li>• Institutional page</li> </ul>

### **Reasons for Choosing the Collaborative IRB Training Initiative**

Kaiser Permanente, Southern California chose the Collaborative IRB Training Initiative for many reasons (Table 2). Managing the user friendly operational aspect of the course is for the IRB staff. Training can be completed by the user all at one time (one sitting) or separately (multiple sittings), which was important for Kaiser Permanente, Southern California as there are many medical centers and many researchers in different locations. People have access to the course 24 hours a day, 7 days a week so that they can work on it at any time. The Collaborative IRB Training Initiative also proved to be cost effective for the organization. In addition, Kaiser Permanente, Southern California liked having the option of posting institution-specific instructions for users; for example, institutions that do not collaborate with Veterans Administration hospitals often do not require their investigators to complete that particular module. The grade book feature allows users to view the modules they have completed and determine which quizzes they still need to complete. Upon completion of the program, users receive a printable certification of completion. For a nominal fee, users can also apply for CME credits at the end of the course. Kaiser Permanente, Southern California receives a weekly spreadsheet that lists registered user names, total points, quiz scores, and program status. The continuing education module enables users to update their certification at an interval designated by their institution without completing the entire core program again.

Registering for the Collaborative IRB Training Initiative is easy and fast for users. They go to the Collaborative IRB Training Initiative link and

complete a single screen registration form. After receiving a user name and password, users can log on at any time and begin the training course. They receive step-by-step instructions, information on how to complete the training course, and when to do the Kaiser-specific page at the end of the course. Users have the option to print a hard copy checklist if they do not want to complete the training at one time.

**Table 2**  
**Reasons for Choosing the Collaborative IRB Training Initiative**

- User Friendly
- Training can be done at once or separately
- Access 24/7
- Cost effective
- Limited customization
- Grade book feature allows users to see which quizzes they need to complete
- CME credits
- Printable certification of completion
- Institutional reports (user feedback forms, confirmation of completion, weekly spreadsheet)
- Continuing education module for subsequent certification