

Collaborative Institutional Training Initiative (CITI)

By Paul Braunschweiger

Paul Braunschweiger, Ph.D., and Karen Hansen of the Fred Hutchinson Cancer Research Center founded the Collaborative Institutional Training Initiative (CITI) Program in March 2000. The Program began developing new educational content in the area of human subjects protection soon after DHHS announced its human subjects protection education mandate in June 2000. The co-founders recruited experts in research ethics and ethics committee procedures to write 10 modules for a new web-based course. Version 1 of the CITI Human Research Subjects Course was written, edited, peer-reviewed and implemented in the University of Miami distance learning software on September 3, 2000 to meet the October 1, 2000 NIH deadline.^{1,2}

In the last nine years, this first course has undergone numerous upgrades, additions and modifications. In addition to this basic course in the protection of human subjects (biomedical and social/behavioral focus), the Program now offers courses in Good Clinical Practice (GCP), health information privacy and security (HIPS), responsible conduct of research (RCR), lab animal welfare (LAW), and a new course in biosafety and biosecurity.

The CITI Program, based in the Office of Research at the University of Miami, is sustained by institutional subscriptions, as well as by grants from the NIH and contracts from the DHHS Office of Research Integrity, U.S. Department of the Navy, and U.S. Department of Energy.

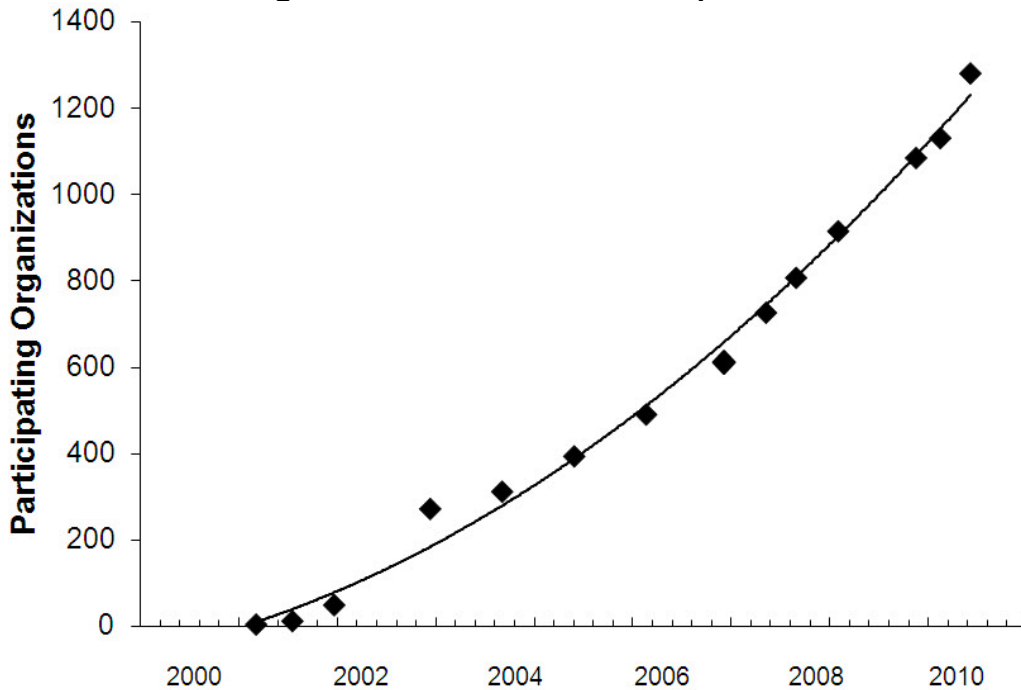
The CITI Program has enjoyed an active collaboration with the Department of Veterans Affairs (VA). In 2003, Braunschweiger and Michael Fallon, DVM, Ph.D., of the VA started a collaboration to develop a new interactive, web-based platform to benefit both VA and CITI educational programs. Released in May 2004, it included a new human subjects course for investigators in the social and behavioral sciences.

Figure 1 shows the exponential growth of CITI institutional subscriptions. Currently, more than 1,250 institutions subscribe to the CITI Program. Table 1 profiles the subscriber base. As of December 2009, 36% were universities, 36% were medical centers, healthcare organizations and VA facilities, 8% were small colleges, 7% were other government departments, and agencies, and 5% were institutions based outside the U.S.

Table 1. CITI Subscriber Profile (n=1201)

Site Category	US	Non-US
Universities	36%	3%
Medical Centers	15%	2%
US Department of Veterans Affairs	14%	
Small Colleges	8%	
Healthcare Organizations	7%	
Government	7%	
Independent IRBs (ERCs)	4%	
Small Clinics	3%	
Industry	2%	
Research Institutes	2%	
Contract Research Organizations (CROs)	1%	
Professional Societies	<1%	

Figure 1. Institutional Subscriptions



International Program

The CITI Program has a very active international program. Currently, the CITI Program is being used at more than 60 sites in 40 countries. The CITI course website (<http://www.citiprogram.org>) is multilingual. Selected course materials are available in English, Spanish, Portuguese, French, Russian, Chinese, Japanese, Korean and Thai. CITI International Centers of Excellence have been established in Canada, India, Korea, the People's Republic of China, Peru, and Taiwan. These Centers, with the help of the central CITI Program, are responsible for the development of local language and culturally appropriate materials for the country or region. In most instances, international clinical scientists and ethicists have driven the establishment of CITI International Centers in their countries.

As the number of clinical trials conducted in the U.S. decreases, clinical trials in emerging economy nations are on the rise.³ The greatest rate of increase is being seen in India, China and Eastern Europe because of high accrual rates from large and diverse potential subject pools, an increasing number of competent international investigators, and the markedly lower costs of conducting trials in these countries.^{3,4} Training of ethics committee members in basic human subjects protection and GCP will ensure that international trials will not only be conducted ethically, but that ethical conduct will be appropriately documented following international standards and guidelines.

While the training of ethics committee members has been a major focus internationally, investigator training is lagging behind because, unlike the U.S., most countries do not have federal mandates for investigator training. As more Federal-Wide Assurances (FWAs) are granted to non-U.S. entities, the need for more capacity to meet investigator training requirements will continue to escalate. Although Internet access is still relatively limited in most low-resource countries, it is increasing at a remarkable rate in some countries, notably India and China.⁵ Thus, cost-effective Internet-based learning approaches are not only

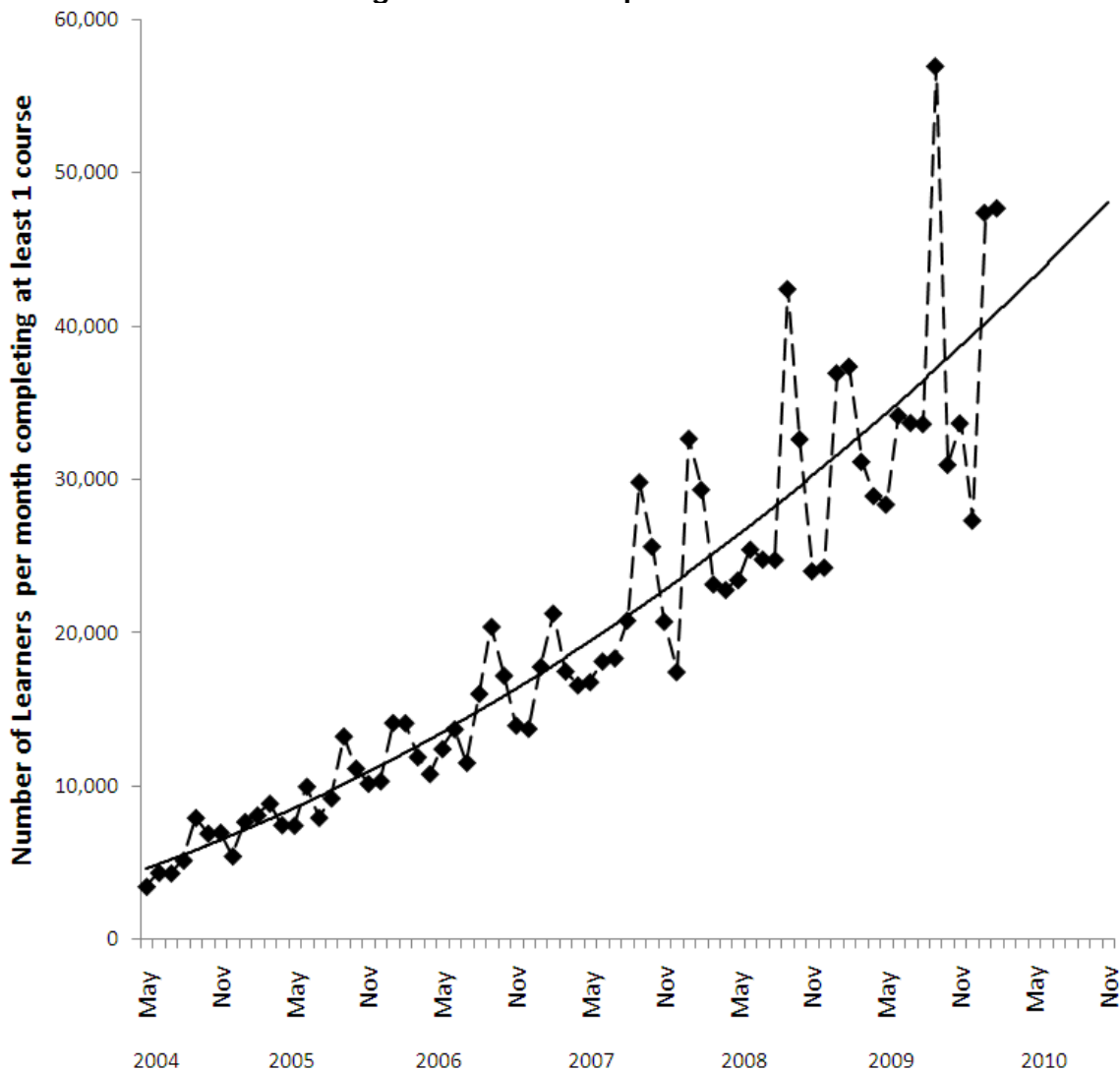
becoming more practical in many low-resource countries, but they may be essential to their research communities.

Organizational Structure

The CITI Developer Group of approximately 75 volunteers meets semi-annually to review the CITI Program. The Developer Group is divided into Working Groups, one for each of the CITI courses. Working Group members review new content, review feedback from learners, and make modifications to the content and quizzes as appropriate. All materials that go onto the course website are extensively vetted by the CITI editorial board (founders and working group leaders) and peer reviewed by outside experts, as necessary. The 10-member Executive Advisory Committee (EAC) provides advice and governance to the co-founders. The EAC Chair is Ernest Prentice, Ph.D., Associate Vice Chancellor at the University of Nebraska Medical Center.

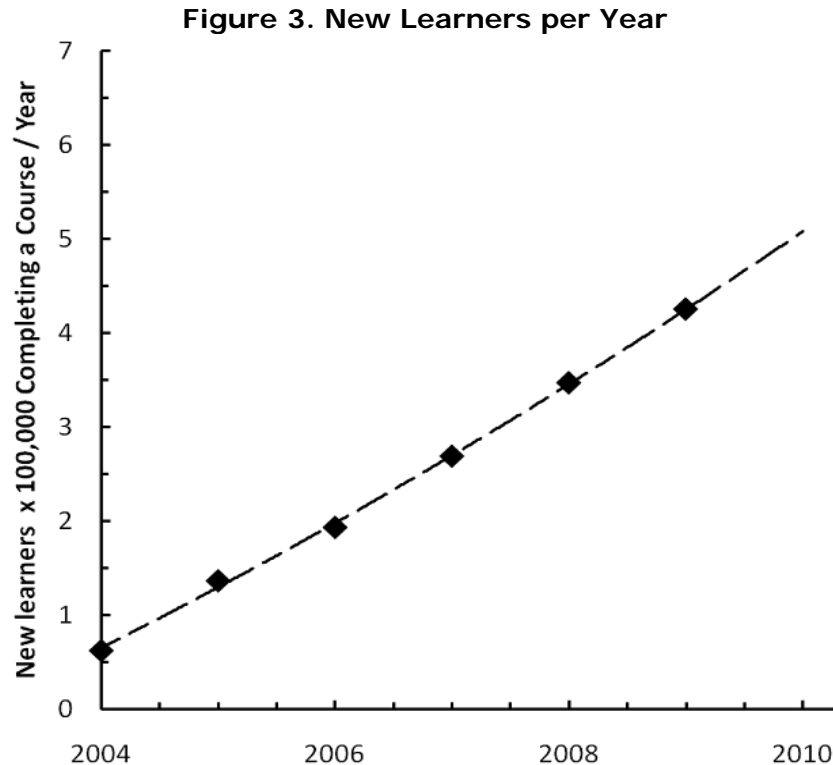
The CITI Program administrative center at the University of Miami provides telephone and Internet access to CITI Helpdesk content specialists, who answer questions from learners and help institutional coordinators set up the courses for their research communities.

Figure 2. Learners per Month



Program Usage and Curriculum

The Program's rapid growth over the past 10 years is evidence of substantial demand for high-quality, web-based research ethics education. Figure 2 shows that monthly usage has increased approximately 10-fold since 2004. Currently, the Program provides research ethics training to approximately 35,000 new learners per month. Peaks in activity in September and January of each year coincide with NIH grant deadlines and students returning to their universities and colleges for the fall and winter semesters. In 2009, more than 425,000 new learners completed a CITI course (Figure 3) and, since 2004, more than 1.3 million people have done so. In other words, one-third of all learners to date completed their first course in 2009.



The Program consists of libraries of modules that can be electronically packaged to provide a seamless curriculum for any number of "Learner Groups." For example, the Human Subjects Protection Library contains 21 modules for biomedical or social and behavioral researchers. In addition, member institutions can include institutional or country-specific training materials in their own, customized curricula. For example, Rockefeller University developed a series of 10 modules on informed consent for their human subjects protection courses.

Courses in the responsible conduct of research are discipline-specific (e.g., Biomedical, Social and Behavior, Engineering, and Humanities). The courses include a short introductory video vignette, a foundation text, case studies, and a quiz. Table 2 shows that the human subjects protection course is used by 97% of member institutions, with all other courses showing significant growth.

Attendant use of CITI courses has also increased markedly. Table 3 shows the increase in monthly CITI course completion rates over the past three years. While monthly course completions have increased for all CITI courses over the past three years, the most rapid percentage growth has been in the RCR Course (+324%) and the GCP Course (+179%).

Table 2. Number of Institutions Using Each CITI Course

Course	Year	
	2009	2010
Human Subjects Research	1,112	1,220
Good Clinical Practice	285	387
Responsible Conduct of Research	222	357
Lab animal welfare	311	356
Health Information Privacy and Security	152	192
(Total CITI Subscriber Institutions)	1,185	1,258

In March 2010, the CITI Program released a new library of 34 modules on various aspects of biosafety and biosecurity. From this new library, institutions will be able to construct biosafety courses for investigators, people responsible for shipping hazardous materials, people working with infectious agents, biosafety committee members, and new institutional biosafety officers.

Table 3. Monthly CITI Course Completion Rates

Course	Year		
	2008*	2009*	2010**
Human Subjects Research	30,428	37,122	52,402
Responsible Conduct of Research	1,573	2,596	6,671
Lab animal welfare	3,414	4,506	5,456
Good Clinical Practice	1,205	2,001	3,361
Health Information Privacy and Security	644	979	956
All Courses	35,389	47,067	68,845

* Completions per month averaged over 12 months

** Completions averaged over the first 2 months of 2010

Conclusion

After nearly 10 years, the mission of the CITI Program remains to provide the best, most comprehensive, and most cost-effective educational platform available to help investigators conduct their research to the highest ethical standards.

The CITI Program has become the most widely used web-based research ethics education program in the world. It has been widely adopted as a basic component of research ethics education for ALL members of the research team. Changes in the Program's name have paralleled this growth. In the beginning, when CITI just provided training in human subjects protection, CITI stood for "Collaborative IRB Training Initiative." As the program grew and CITI started adding new courses in LAW, HIPS and RCR, the name was changed to "Collaborative Institutional Training Initiative." Now that the Program is being used in 40 countries in multiple languages, CITI might soon stand for "Collaborative International Training Initiative."

The popular media's attention to unethical activities in science has contributed to an erosion of public trust in the clinical research enterprise. CITI believes rigorous research ethics training promotes sound ethical practices and serves the public's trust. Ethical behavior by the research community is more than public relations and even regulatory compliance; it is just the right thing to do.

References

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