

ARCHIVE NEWS RELEASE

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NIH Clinical Center Develops On-line Course for Clinical Research Training

Bethesda, Maryland — An interactive on-line course on how to conduct clinical trials is currently available on the National Institutes of Health [Clinical Center web site](#).

The course was developed by the NIH Clinical Center to teach essential principles and processes to conduct clinical research at the Clinical Center. About 900 protocols are currently being conducted at the 13-story facility on the NIH campus in Bethesda, MD.

"Historically, investigators depended on willing and able mentors to teach the intricacies of clinical research. That approach simply doesn't work today," said Dr. John I. Gallin, Clinical Center director, who was instrumental in developing the course. "Clinical research can be beneficial and successful only when physician-researchers have the necessary training and expertise to conduct it."

The course was instigated by guidelines developed in 1996 by the International Conference on Harmonization, a consortium of regulatory bodies for Europe, Japan and the US that define resources required for clinical principal investigators. Based on these guidelines, the Clinical Center Medical Executive Committee developed a set of standards that provide essential principles and processes for conducting clinical trials within NIH intramural research programs. One of those standards designated training and education to ensure clinical researchers have a consistent and complete understanding of their responsibilities.

The course provides the training and structure needed to conduct research protocols that protect patient safety and assure quality results. It also encourages consistency in data collection and storage so that there is wide access to methods and results.

Course topics cover ethical issues in human subjects research, roles and responsibilities of the investigator and the institution, regulatory issues and interacting with the mass media.

The course is required for all clinical principal investigators conducting trials at the Clinical Center. It was first conducted last year, with two live sessions in September and December. Four-hundred researchers took and passed the course in those two sessions. A video version was installed on the Clinical Center's website in Jan. 2001, and the interactive web-based version has been tested on the site since early March. One hundred fifty-one people have taken and passed the course on the web.

"While only intramural NIH researchers can receive credit for the course, we invite anyone to take it who can benefit from it," said Dr. Gallin. "We encourage other institutions to use this course as a base for their own training programs, and we're interested in comments and feedback as we refine the course," he concluded.