

# THE PARTICIPANT

THE PATIENTS' PERSPECTIVE

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## Volunteers say site staff is crucial to involvement

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**S**tudy volunteers have several motivations for participating in clinical trials, but one of the important factors is the warm, professional care and attention they receive from the site staff during the trials.

Those are among the key findings that emerged from three focus groups conducted by Kenneth A. Getz, CISCRP Founder and chairman, and Diane Simmons, President and CEO of CISCRP, in March in Winston Salem, NC. The focus groups are part of an ongoing effort to gather primary research and gain a deeper understanding about study participants.

CISCRP is preparing a White Paper that discusses the focus group findings in more detail, but the preliminary findings are cited below. One very critical factor that played a key role in attracting first-time participants and repeat volunteers emerged:

**The patients' connection with the trials investigator and study staff is crucial in creating a positive experience. This valuable feedback points out that clinicians' efforts toward friendliness and consideration are noticed and appreciated.**

These interactions included a number of areas:

*Personal connection:* Many focus group members noted that their relationship began with an already-established association with someone who either participated in a trial or worked at the trial site.

*Staff was organized, prepared, responsive, and coordinated:* Volunteers commented that the site operation was professional, and they trusted the site staff to take excellent care of them.

"It's just like a doctor's office. I really enjoyed the fact that they followed up and did what they said they were going to do," said one volunteer.

*Staff held volunteers accountable while helping them maintain a positive outlook:* Study participants appreciated that the site staff made sure the volunteers stuck with their regimen and took their health seriously, while keeping them positive and motivated.

"I like the fact that you have to be accountable. It's like having to check in and see what you've been doing and it keeps you on target," said one volunteer. "They made sure I took my health seriously," said another.

*Staff was accessible at scheduled and unscheduled encounters:* The site staff's willingness to accommodate volunteers' schedules made a highly positive impression.

"Lots of times I wanted early morning, like 6:30 or 7:00 a.m. I don't think my staff person was really a morning person, but she came in so I really appreciated that," said one volunteer.

*Warm, positive relationships with the staff and a sense of humor were important:* When asked what they liked best about the clinical trials, a majority mentioned the site staff. One man commented, "You kind of develop a personal relationship with the staff. It's not just about the study." Another volunteer said, "The attitude of the physicians and staff just blew me away."

CISCRP's White Paper also includes information about volunteers' reactions to the consent form; how they evaluate risk; and their likes and dislikes about clinical trials.

CISCRP's focus group findings suggest that there is a huge opportunity for study sites to conduct their own internal assessments of staff behavior and attitudes, and how those can affect their relationship with patients. By conducting such studies, site personnel may gain important insights into ways the staff can contribute to a more positive experience for clinical research volunteers.

To receive a copy of the White Paper when it becomes available, please send an e-mail to: [info@CISCRP.org](mailto:info@CISCRP.org)

# When a clinical trial closes unexpectedly

**A**lthough it is rare, a sponsor may unexpectedly halt the investigation of a new compound before studies are complete. Knowing the correct closure procedures in advance enables site workers to be ready to protect the safety – and continued motivation – of the volunteers.

Early trial terminations affect both the study and the study subjects. Site workers have to handle activities for all study subjects within a short time frame. Volunteers may miss out on a beneficial treatment; they may be concerned about their health if the drug has been found to be unsafe, and completing the study early can be inconvenient.

Communicating well with the sponsor and with the study subjects will ensure a reasonable resolution to an unexpected clinical trial termination.

CISCRP is offering a new brochure that tells site personnel how to properly conclude a clinical trial that has been terminated unexpectedly. To receive a copy of the brochure, please write to [info@ciscrp.org](mailto:info@ciscrp.org).

***When an early site closure occurs, the site director and personnel should ask:***

- Is the study being closed for safety reasons?
- Do the subjects need to have their study medication tapered, or can it be withdrawn abruptly?

***If the study is being closed for safety reasons,*** clinical trials personnel must contact the subjects immediately, tell subjects to stop their drug, and schedule them for a visit to return their unused drug and complete necessary final evaluations, lab tests, etc.

***If the subjects' drugs need to be tapered off at the end of their use,*** this drug-dependent situation needs to be addressed. Clinicians will need to schedule all study subjects for a visit to explain and start the taper period.

Site personnel can make the closing process smoother by using a checklist of activities to perform when a trial is terminated early. Start with the basic checklist at right:

## CHECKLIST OF ACTIVITIES FOR UNEXPECTED SITE CLOSURE

- ✓ **Ask the sponsor:**
  - Why the trial is being terminated
  - Is it for safety reasons?
  - Determine the need for any long term safety follow-up
- ✓ **Determine if subjects can have the drug stopped abruptly or does it need to be tapered.**
- ✓ **Arrange for the necessary time and personnel to handle the subject discontinuation visits**
- ✓ **Contact (telephone) each study subject:**
  - Explain why the trial is being stopped
  - Explain any safety concerns, and tell what is being done to ensure the subject's safety
  - Describe the process for tapering the drug, if applicable
  - Explain the need to come in for a final study visit and for any necessary tests, etc.
  - Reassure the subjects that their safety is of paramount importance
  - Schedule the discontinuation visit(s) for each subject
- ✓ **Complete the necessary study visit(s) for each subject.**
  - Answer any questions about the study and/or the termination
  - Thank the subjects for participating
- ✓ **Complete the final case report forms according to the sponsor's instructions.**
- ✓ **Stay in contact with the sponsor** throughout the closure process to ensure that all activities are completed and that any subject-specific concerns are addressed
- ✓ **Remember to complete all the usual study closure activities, including:**
  - Completion of case report forms (CRFs), including error corrections and data queries appropriate review, filing, and storage of all study documents
  - Return any unused study drug or materials to sponsor
  - Submission of a final report to the sponsor and to the IRB.

# Controversies in Clinical Trials Globalization

**A**s new information and important issues arise, CISCRP wants to help clinical trials professionals keep up to date. Here are some recent articles you'll want to take a look at:

### ***Ethical and Scientific Implications of Globalization of Clinical Research***

From *The New England Journal of Medicine*, Feb. 19, 2009  
Seth W. Glickman, M.D., M.B.A., John G. McHutchison, M.D., Eric D. Peterson, M.D., M.P.H., Charles B. Cairns, M.D., Robert A. Harrington, M.D., Robert M. Califf, M.D.

Clinical trials are becoming increasingly globalized; yet trials done outside the established trial regions raise ethical and scientific concerns, according to the study authors.

While globalization of clinical trials may lower costs, says Glickman, downsides include:

- Ethical concerns about the lack of trial oversight, different standards and approaches to conducting clinical trials, and the monetary lure for subjects in low-income countries;
- Drugs may react differently on 'drug naïve' people in developing countries (i.e., people who have had little or no prior medication) than they do in residents of Western countries, thus, results can not be generalized;
- Genetics, cultural, and social factors influence drug metabolism, so these factors could make trial results less relevant to a US population.

<http://content.nejm.org/cgi/content/full/360/8/816>

### ***Responding to Emerging Queries on the Legitimacy and Validity of Globalization of Clinical Trials***

From *Clinical Trial Magnifier* Vol 2:3 March 2009  
Johan PE Karlberg, MD, PhD, BSc

Karlberg responded to the New England Journal of Medicine article (at left) and to an article from the European Medicine Agency, entitled *Reflections Paper on the Extrapolation of Results from Clinical Studies Conducted Outside Europe to the EU population*.

Karlberg noted some valid points in Glickman's article, stating that the high illiteracy rate and lack of public health

care in emerging countries could lead toward unethical behavior in administering clinical trials.

However, he noted that many emerging countries have developed excellent infrastructure and practices for clinical trials.

Glickman's assumed cost saving of conducting clinical trials in emerging locations is incorrect, says Karlberg, as are claims that easier regulatory environments will lead to greater access to expanding markets; or expectation the accelerated recruitment will occur.

Karlberg also disputed the second paper, whose premise was that in global clinical trials, different medical practices, disease definition and study populations may make the foreign data non-applicable to an EU setting.

<http://www.clinicaltrialmagnifier.com/download.aspx?id=0c311436-7ee3-4bf3-8429-1375a64187fc>

### ***Elusive Sponsor-Site Relationship Global clinical trial landscape changes pose new challenges for all sites – even AMCs.***

From *Applied Clinical Trials*, Feb. 1, 2009  
Kenneth A. Getz

Getz discussed important trends and challenges in globalization, privatization, and changes in size and scope of clinical trials sites. He calls for creative solutions and an investment of personnel and resources to establish successful sponsor site collaborations.

He pointed out the steady growth in the proportion of investigators in emerging regions, also noting that there has been a decline in the number of active FDA-regulated investigators conducting phase II and III trials in North America, while the opposite has occurred in Phase I studies.

Competition for clinical trials will intensify in the near future, according to Getz. The number of investigators per active IND has nearly doubled in the past decade, yet the average number of patients per NDA has declined by half. Sponsors are engaging more investigators to recruit fewer patients per IND.

<http://appliedclinicaltrialsonline.findpharma.com/appliedclinicaltrials/Project+Management/The-Elusive-Sponsor-Site-Relationship/ArticleStandard/Article/detail/579328?contextCategoryId=43300&searchString=elusive%20sponsor>

# New Medical Heroes Community Membership

**C**ISCRP's mission is to educate the public about clinical trials and to recognize volunteers' contributions. To this end, CISCRP has developed a program exclusively for clinical trials volunteers, which was announced through our new Medical Heroes newsletter. [http://www.ciscrp.org/quarterlyupdate/apr2009/MedicalHero\\_April2009\\_web.pdf](http://www.ciscrp.org/quarterlyupdate/apr2009/MedicalHero_April2009_web.pdf)

In this new program, all clinical trials participants can become a member of the Medical Heroes Community. Membership benefits include:

- Free bi-monthly Medical Heroes newsletter
- Invitation to attend a free public education program in their community (AWARE for All-Clinical Research Education Day) where they will be recognized as a Medical Hero and receive a gift
- Online social network known as "Clinical Research Volunteers Community" that connects patients, families, friends and caregivers for support and inspiration.... <http://community.ciscrp.org>
- Assistance in locating clinical trials through [www.SearchClinicalTrials.org](http://www.SearchClinicalTrials.org) or by calling 1-877-MED HERO
- Being recognized and honored during the "National Medical Heroes Day"

The look and feel of the Medical Heroes newsletter ties in with CISCRP's new public service announcement (PSA) campaign developed with pro bono assistance from Ogilvy Healthworld, a division of Ogilvy & Mather.

## New tool for finding clinical trials results

CISCRP has developed and launched one of the most comprehensive, personalized clinical trials search tools within the industry. The new tool, Search Clinical Trials, which can be found at [www.SearchClinicalTrials.org](http://www.SearchClinicalTrials.org), offers several ways for members of the public, patients, family members and health care professionals to find clinical trials, clinical study results, and medical news.

- Search Clinical Trials users can:
- Search multiple websites for clinical trials and trial results

- Find a clinical trial by selecting a medical condition, geographic locations, and how far they're willing to travel

If patients need additional assistance they can:

- Receive a free custom search by calling CISCRP at 1-877-MED HERO and speak with a staff member who will perform a search based on the criteria requested or
- E-mail their search request to [info@ciscrp.org](mailto:info@ciscrp.org)

Once CISCRP receives their request, the staff will search dozens of websites and clinical trial registries. We will print out the results of our search and highlight the purpose of the study; the study name and ID number; eligibility requirements and contact information.

The search results will then be mailed to the individual along with an educational brochure to help prospective patients make an informed decision about participating in a clinical trial. All searches are private and confidential.

## Help support patient and community education about clinical trials

CISCRP has numerous new and ongoing initiatives aimed at educating and empowering patients to be active participants in the clinical research process. CISCRP programs also provide resources for the research community to better understand the study volunteer.

Our new clinical trials search service, Search Clinical Trials; our recently-launched Medical Heroes campaign and Community membership program; AWARE for All- Clinical Research Education Days; our focus group studies, our educational materials, and our other activities are important undertakings aimed at increasing awareness of clinical trials.

"We invite individuals and companies to join our efforts to increase awareness of clinical trials among patients and the overall community," says Diane Simmons, President and CEO of CISCRP. "Your generous donations help support our ongoing efforts to increase and promote education about clinical research participation."

You can make your donations online or by check. For instructions, go to [www.ciscrp.org](http://www.ciscrp.org) and click on Giving.