



Research Participant Concerns

Factors That Most Inform and Educate Clinical Research Participants:
Findings from CISCRP Focus Groups with study volunteers

If you have any questions about this research, would like to suggest useful information to include, or to speak with CISCRP about conducting a study please contact us at info@ciscrp.org

Visit www.ciscrp.org for news and updates about our nationally recognized programs and events.

The Center for Information and Study on Clinical Research Participation (CISCRP)

501(c)(3) nonprofit organization

Support our mission to educate and inform on clinical research participation!

INTRODUCTION and METHODOLOGY

In 2009, CISCRP conducted a series of focus groups among study volunteers to probe for factors that most inform and educate clinical research participants. This research is one of many original projects that CISCRP regularly conducts in support of its mission to study various aspects of clinical research participation.

Focus groups were conducted in March 2009 among a convenience sample of 22 study volunteers in active clinical trials conducted at PMG in North Carolina. Three focus groups were held, each lasting approximately 90-minutes. Participants groups were as follows:

- Group I included eight participants aged 31 to 50;
- Group II included six participants under 30;
- Group III included eight participants over 50.

Prior to the interviews, each volunteer provided signed consent to participate and to be recorded with audio-video equipment during the session. For their participation, volunteers received a meal and an educational book about clinical research.

Each group had even numbers of male and female participants, with a range of socioeconomic backgrounds and medical histories. Most focus group participants had completed participation in one or two clinical trials, though a few older participants were engaged in their fifth or sixth trial. Participants in the youngest age group primarily participated in treatment studies of interventions already in use, such as flu or tetanus shots and contraceptives. Participants in the two older groups were more likely to have taken part in clinical trials related to their current or anticipated health problems, including obesity, diabetes and hypertension.

SUMMARY STUDY FINDINGS:

A. Focus Group participants reassert the essential role that study staff and health care professionals play in volunteer recruitment and retention. These individuals are central to establishing trust, rapport and motivation to comply with participation requirements. Focus group attendees consistently describe relationships with study staff as tough but fair; disciplined but supportive.

Discussion: Focus group participants unanimously agree that their personal relationships with study staff influence their decision to volunteer and their willingness to complete participation. The overwhelming majority of focus group participants praised the "support system" of study staff, including physicians, nurses and trial coordinators, as highly skilled, personable and accessible.

For some, the study staff offered a friendly face, an open ear and a level of concern that might have been lacking in their previous medical encounters. One respondent appreciated "the conversation" with a friendly and knowledgeable support staff; another praised the "personal relationship" developed with physicians who "went out of their way to accommodate" volunteers' specific needs.

While many appreciated the study personnel's consistently thoughtful care, some praised study staff for pushing them out of their comfort zone. Especially for those involved in behavior-based trials, the fresh perspective offered by a supportive but demanding network of medical professionals pushed them closer to their health goals. As one post-weight-loss-trial volunteer explained, "sometimes it's not what is said, but it's the way that it's said...having a different dietitian to work with who could...make a workout seem not so...tedious and difficult" injected new energy into the quest to get in shape.

In addition to more control and accountability, patients crave the human connections forged when volunteers feel that they are actively involved in a research study. For one participant, asking fellow volunteers about their study involvement was like drawing together a new team of investigators. Finding out "what else is going on here (at the research center)," sharing perspectives on research experiences and exploring the scope and implications of clinical trials "in a social atmosphere" is "beneficial to us as a community of people."

Following one Group III volunteer's remark about the "family atmosphere" created by a friendly staff and fellow participants, focus group members agreed with the interviewer's comment:

Not everyone has done what you've done in clinical research and you share certain views about how you're helping with the research process, how you're helping the development of medicine...you have a kinship to each other...

Those who acknowledged sharing "a certain understanding" with other participants enjoyed feeling connected to a network of volunteers, medical researchers, trial staff and potential beneficiaries, and were reminded of their key role in advancing medical science.

Young and older focus group participants alike tended toward impulsive, rather than premeditated, enrollment decisions. For the most part, volunteers did not report deliberate planning processes or being over-saturated with recruitment information. Instead, their decisions were based largely on cues that caught their eyes (newspaper ads), ears (peer or professional recommendations), and attention (personal or family health crises).

Notably, the latter two cues involve personal contacts, with friends, family or physicians who have experience with or information about clinical research trials. Focus group members reported establishing their own contacts after their participation, by recommending study participation to friends with specific health or money concerns. The centrality of interpersonal connections in volunteers' decisions to join and remain in trials reiterates the key role personal contact plays in building trust: people are more likely to pay attention to ads or to follow up on referrals if a living person is present to encourage them and answer questions.

In a comment showcasing the primacy of personal contact, one volunteer recalled being anxious about not being able to afford the blood work and medicine she needed to take care of her diabetes after losing her job and insurance. Faced with a health crisis, she responded to an Internet posting about a diabetes study, and the immediate, concerned care she received from the study staff convinced her to become a trial volunteer:

I was so relieved when that person (at the center) comforted me...They helped me with my medicine. They checked my blood work...that to me is a comfort, knowing I can't afford the insurance.

A younger veteran of multiple trials noted that "the conversation" with the research staff and "the fact that...they followed up and stayed on top of what they said they would" provided the boost she needed to join and remain in multiple clinical trials. Like many other volunteers, even though she was initially motivated by the prospect of free access to an intervention she needed, the immediate and sustained support she received from the personable professionals fostered her commitment.

At a time when recruitment and retention strategies and tactics tend to marginalize the role of the study staff and trusted health care professionals, the results of these focus groups strongly suggest the need to more effectively engage these professionals as real assets in the clinical trial process. Potential engagement tactics might include: Educational and communication efforts targeting health care professionals in specific communities prior to trial initiation; involvement of study staff during project initiation; general and targeted communication that positions study staff as partners in the recruitment process.

B. Focus group participants reveal core motivations of all study volunteers regardless of age and socioeconomic status. These motivations serve as a blueprint for patient and public education and outreach. Study volunteers:

- **Want to feel that they are taking control of their medical condition and well-being**
- **Want to develop personal relationships with study staff**
- **Want to be treated as human beings**
- **Want to know that their participation will make a difference**

Discussion: Across focus groups, volunteers regularly expressed a desire to take control of their health in a structured environment. Many recalled wanting to take charge of an existing health issue, but being unable to do so alone or in a traditional medical setting. A clinical research trial's site, staff and protocol offered a supervised space in which they could learn to be responsible for their health.

Participating in medical research as a way to steer personal and public health reinforces the drive toward patient-centered health care. Yet volunteers clarify that "patient-centered" does not mean that they want medical autonomy. Despite common expressions like "take control," study participants do not choose total independence in their efforts

to improve their wellbeing. Following the suggestion that "you feel in control of your health when you are in a clinical trial," participants answered affirmatively, but emphasized a desire for accountability paired with responsibility as described in more detail below.

Many interviewees - particularly those who had completed trials prescribing healthier eating or activity levels - equated their decisions to enroll in studies with resolutions to make lasting lifestyle changes. Feeling obligated to themselves, their families and the study staff buoyed their efforts to adopt healthier habits. One volunteer recalled joining a weight loss trial in order to "get in a good pattern with exercise and eating right on my own and with the help of the dietitian here (at the site)" so "that I can really make it outside of research." Another volunteer spoke similarly of wanting to "change my lifestyle," driven by the prospect of "being accountable and getting on [a] scale in front of somebody" as a study participant.

The prospect of being accountable to the research coordinator spurred and sustained volunteers' interest in trials. They appreciated that "the staff here is always making sure that we're doing what we're supposed to do." Another volunteer testified to the appeal of linking a desire for a healthier lifestyle with a network of medical professionals to reinforce new exercise and eating routines: "I really liked having the medical supervision while I was losing the weight; that was a big draw."

Volunteer-study staff relationships form and solidify at several critical junctures. With the right messages and modes of communication, research sites can reach out to potential volunteers at decisive moments and invite them to begin conversations that could grow into lasting commitments to the center and its staff. To be effective, the education provided before and after trials must reflect what volunteers expect, need and want to know about clinical research.

Focus group members felt more prepared to enroll in trials after unraveling dense informed consent documents face-to-face with coordinators, and valued the medical and emotional support sustained throughout their participation. Recalling friendly exchanges with an approachable research team led all three groups to a similar conclusion: as participants, they are human volunteers, not lab equipment, and they appreciate the interactions that support that distinction.

Volunteers in all age groups renounced the "guinea pig" label that is often ascribed to clinical research participants. As one volunteer explained, the term "guinea pig" belongs in the last century, before regulations defined Good Clinical Practice. Some participants further rejected the commonly used expression "research subject," and preferred the term "volunteer," because "'subject' always sounds very scientific" and "'unlike a person'."

One participant went beyond "volunteer" to suggest a new idiom:

I like the term 'concerned citizen.' I'm a concerned citizen. What I do may not help me...but I've got children, I've got grandchildren... If there [were] a particular study or medication that turned out to be approved by the Food and Drug Administration...and their doctor prescribed it for them, and it cured them or helped them live a better life...I'm concerned about that. So 'concerned citizen' fits a whole lot better in my vocabulary.

Labels like "guinea pig" and "research subject" turn participants into passive recipients of investigational drugs and procedures. As "volunteers" and "concerned citizens," they become active participants, aware of the risks and benefits involved in their decision to join a trial. A Group I participant enrolled in a trial because "I didn't want to be...my own guinea pig...in terms of not being aware of what was going in my mouth everyday." As a self-aware research volunteer, the participant can claim an active role in his or her wellness, and find a level of control that might otherwise be out of reach.

While having an incentive to enroll in a clinical trial is a necessary first step, the process of choosing to participate continues beyond the initial recruitment notice or contact. Volunteers in each focus group described weighing their incentives, such as increased control, personal or public health improvement, or other compensation, against the risks of participation. The information and perspectives they used in their decisions to participate serve as bedrocks for pre-enrollment education. Two themes are particularly notable:

1. Volunteers are more likely to act on a chance to participate if they recognize the potential benefit to personal or public health.
2. With respect to concerns about risk - volunteers are most interested in understanding potential adverse events and the requirements of their participation (e.g., number of visits, trial procedures).

Pre-trial educational interventions also need to incorporate acknowledgements of potential volunteers as human actors, whose concern for their own and others' welfare makes them a vital part of medical research. Pre-trial education should emphasize the non-material benefits of volunteering and give clear, consistent explanations of the key elements of participation, including the research procedures and the volunteer's role. If instruction is linked to personal contact, potential volunteers will be better equipped to make informed decisions and remain confident throughout the trial. Further education must extend initial connections between volunteers and the center to ensure their overall satisfaction and to encourage their sustained involvement as participants and advocates.

Clinical trial education typically comes from the staff during interactions. Warm and caring interactions make it easier for patients to feel comfortable enough to ask questions without the fear of being bothersome. These interactions also provide the opportunity for clinicians to give more information about the clinical trial process and the importance of participation.

The post-trial follow-up is a pivotal moment when research centers can reinforce the relationships built before and during the study volunteer's enrollment period. Education provided after a trial's conclusion will benefit the growing population of volunteers clamoring for information, while strengthening the research center's backbone of satisfied, active participants.

Volunteers who see themselves as having "invested" their "time and bodies" in a trial, perceive finding out the observed side effects or status of the investigated therapy as both appealing and necessary. Focus group volunteers of all ages were eager to learn about the outcomes of their particular trials. Several indicated that having access to the research results would help them feel more confident and more satisfied with their participation experiences.

A number of focus group respondents regretted not knowing exactly what role they had played in a study (whether they had been in a control group or a test group, for example), or how the results of their participation would be applied. Medical research reports often involve as many technical terms, abbreviations and symbols as the detailed protocols outlined in informed consent documents. On the tail end of a trial, however, veteran participants typically no longer have the benefit of an attentive study staff to guide them through unfamiliar jargon.

Study volunteers want follow-up contact after their trials. Post trial education needs to include relevant study results and consistent interactions to ensure volunteers continue to feel valued even after their last site visit. Research professionals can give their volunteers the education, enthusiasm and support they need to become public educators themselves.

C. Focus group participant perceptions of common clinical research practices are having intended and negative consequences. The 'last patient last visit' mindset shared by clinical research professionals alienates study volunteers and creates a sense of discontinuity. The act of participation does not create an enduring connection to the clinical research enterprise for study volunteers.

Compensation and participation incentives attract attention to promotional communications but may cheapen and trivialize the value of participation to society and the advancement of health and medical knowledge.

Discussion: Focus group participants agreed that the "unusual experience" of being in a clinical trial puts them in a unique segment of the population. Most, however, perceived their role in the research as ending with their final site visit. Several members of the youngest group reported abrupt terminations to their trials, with unfulfilled promises of information on either concluded or upcoming studies. Without post-trial follow-up from the research center, they were left unsure of the details of their participation, such as how specific therapies fared in the study.

Lacking a sustained relationship with the research center and staff, and without organized forums for questions or discussion, past volunteers seem little inspired to talk about research, even with each other. One young participant admitted that despite having "friends and family members that do trials," they "never sit down and have a meeting about it" or share experiences. They treasured the relationships forged during trials, but felt little lasting connection to clinical research. Such a viewpoint could impede their future participation or willingness to spread support for participation as informal advocates.

Many focus group members felt that their connection to a center ended with their final visit or payment. The challenge for the research community is to tip the balance, so that most participants feel more deeply connected to their role in medical science. Educational approaches therefore must emphasize the knowledge and health benefits

that can be both gained and given through trial participation, the concern and compassion required to contribute to clinical research, and, above all, the supportive personal relationships that will help participants and professionals achieve their research goals.

Building and maintaining a community of volunteers, researchers, physicians and other study staff is necessary if the medical research industry hopes to expand and strengthen its participant base. Constant communication, through conversations between volunteers and study personnel, informational forums for participants in specific trials, and post-trial resources, will ensure that volunteers stay aware of ongoing study opportunities and feel more than a transitory connection to clinical research. Investing in personal relationships – between volunteers and their study staff or other participants – is a pivotal element in successful education.

Focus group participants' comments show that money-focused recruitment campaigns and comparisons of research volunteers to "guinea pigs" or "lab rats" depersonalize the trial experiences and keep them from feeling like they are truly part of an extended research team. Typical perceptions of clinical research participation must shift before people can take part proudly and comfortably in a research community.

The emphasis on monetary compensation in media and recruitment rhetoric impedes public and participant recognition that volunteers are part of a vital exchange, in which they are compensated for sacrificing their time, effort, and even physical welfare.

Several volunteers offered indirect suggestions for ways to reshape how participants – and eventually the rest of the research industry, the media and the general public – view their role in clinical trials. Volunteers who are not encouraged to build personal connections with their trial and the long-term impact of clinical research are reluctant to appreciate their participation:

If I gave a kidney to a stranger you could call me a hero. But to come in here and weigh in and get paid to do it, that's just wrong. [Group III]

One young participant reflected that people would be more inclined to view volunteers as "heroic" if they demonstrated interest in the investigational purpose and health benefits of clinical trials.

Volunteers want to be treated *like* people *by* people. Taking the time to listen, talk to and build relationships with participants will pay off: volunteers commit to trials when they feel accountable to themselves and the staff to act responsibly. Supporting participants as valued individuals ensures their trust, obligation to the study and staff, and a more accurate and appealing view of clinical research within and beyond the trial site.

D. Focus group participants affirm the importance of education and outreach that provides consistent messages, emphasizes the importance of study staff, and is delivered in a variety of formats to accommodate different learning and decision-making styles.

Discussion: One young volunteer drew on an established relationship with a friend working at the research center to supplement the official informed consent process and fully understand the implications of his decision to participate:

I knew every single detail about how the study was going to go before I even came in to do it...I asked a lot of questions because I was a little nervous, because I didn't know anything about drug research. [Group II]

Volunteers' willingness to sign up for and stay with a clinical trial depends on their understanding of the study protocol and their potential participatory role. This comprehension is enhanced when they can discuss the risks, benefits and procedures with a demonstrably caring research professional.

Yet even when a face-to-face informed consent process is established, participants can still lack complete or enduring comprehension of the basic concepts that define many trial protocols. In the focus groups, for example, some volunteers did not have good grasp of study-defining words like "placebo-controlled," and could offer only hazy speculations on the scientific purpose driving their particular study. Many admitted to skimming over the "legalese" in informed consent documents, but still wanted to know the information the pages contained. While it is not necessary to explain every technicality of a research proposal to study volunteers, it is essential to make sure they understand what to expect during their trial, the basic principles guiding the study, and why their participation is

essential to reaching an identifiable research goal. Most importantly, pre-trial education needs to be built around what volunteers want to know – and as the focus groups show, that includes the descriptions often lost to glazed eyes skimming for side effects.

Focus group volunteers' responses suggest that in order to make an informed, confident decision to participate, people need to comprehend the potential public and individual health benefits, the possible risks, and the basic terms and protocols shaping a particular study.

National regulations have begun to address the paucity in post-trial education, but few of the interviewed participants were aware of the system in place for providing clinical research results. The 2007 FDA Amendment Act (FDAAA) required the NIH to expand its research trial catalog to include mandatory posting of “basic results” of registered studies as tabular numerical data on patient population characteristics and outcome measures. The data is available to the public in the NIH web database (ClinicalTrials.gov).

Yet “available” and “accessible” are not synonymous. Recognizing that the lay public is unlikely to understand fully the quantitative reports, the FDAAA includes a provision requiring NIH to extend the data bank to “enhance patient access to and understanding of the results of clinical trials” by September 2010. In anticipation of this mandate, NIH held a public meeting in April 2009, where pharmaceutical and research industry representatives, medical journal editors and others discussed potential guidelines for non-technical study reports. According to industry reports, NIH officials remained “noncommittal” on the question of narrative trial summaries, which some consider potentially subjective or misleading, and are considering FDA-backed guidelines to ensure objective prose.¹

As national bodies work to develop guidelines for readable reports, research centers can respond to the public's call for more accessible information about clinical trials and results by extending the relationships established during site visits. In order to build a durable relationship with the millions of past, present and potential future medical volunteers, research centers must demonstrate that informing and educating patients is a high priority of clinical investigation.

During the focus group interviews, volunteers responded positively to a proposed post-trial newsletter with clear explanations of the study procedures, the results, and other research opportunities. Participants who reported feeling completely under-informed or overwhelmed by Google-retrieved websites when they tried to search for results on their own welcomed the prospect of a personalized report. Some want individualized results indicating their own responses to the investigational drug; others expect more generalized data about the impact of the study on drug development and public health – but almost all saw some form of post-trial information as integral to a satisfactory participation experience.

A newsletter or audio-guide is just one of many channels through which the clinical research industry can reach out to its essential human volunteers. Other possible approaches include inviting participants to return to the study site for a de-briefing session once the results have been collected and reported, or providing a telephone hotline or in-person office hours to allow volunteers to discuss concerns or request additional information. In addition to providing participants with vital information about the results of their trials, such services would encourage volunteers to continue interacting with the research site and fellow participants, and would reassure them that their contributions are indispensable to medical research.

Increasing personal contact with volunteers during and after trials will help keep them engaged in the research community, and will prevent them from feeling deserted once a particular trial is terminated. In addition to providing print, audio, video and web materials, clinical research sites might consider organizing gatherings for past, present and future volunteers. Whether trial-, disease-, gender-, ethnicity- or age-specific, or more universal, such forums could include panel discussions, patient testimonials, follow-up presentations on past trials, overviews of upcoming studies and informal socializing.

As the focus groups show, when people feel connected to a study site or staff, they are more inclined to talk about the research they have been involved in, with other participants, researchers and outsiders. Bringing those people together periodically would reinforce the notion that they are truly a part of the research community, and would increase their contacts with ongoing and upcoming research opportunities. Energized by such meetings and discussions, past and current volunteers might be more inclined to spread the word about their own and others' trial experiences to friends and family. Focusing on building an informed community of researchers (both professional and volunteer) will simultaneously strengthen the existing base of participants and foster a powerful advocating force.

ABOUT CISCRP and WHERE TO GO TO LEARN MORE ABOUT STUDY VOLUNTEERS

The Center for Information and Study on Clinical Research Participation is available to assist you in recognizing and overcoming barriers to public trust and participation in clinical research. Founded in 2003 by Ken Getz, CISCRP is a first-of-its-kind independent nonprofit dedicated to educating and informing the public, patients, medical/research communities, the media, and policymakers about clinical research participation and the role that each party plays as a participant in the process. To date, all of CISCRP's programs and services have been developed through comprehensive stakeholder input--using market research, survey instruments, IRB review and approval, and focus group testing. CISCRP ensures that materials are easy to read, understandable, and visually pleasing to the public. We address the issue of health disparities through customized educational materials for minority participants and the involvement of 30-40% minorities in our public programs. We have demonstrated expertise in facilitating effective collaboration among all members of the clinical research enterprise and we are invested in providing resources for the research community to better understand the study volunteer.

Below are a few examples of CISCRP's educational tools:

Educational Branding Initiative: “Medical Heroes” campaign

In order to improve the public's understanding of their role as active participants in the clinical research process, there is a need for placement of an already-developed public service campaign. Medical Heroes includes a series of recognizable print, radio and TV ads that proudly feature ordinary people of different ages, races and occupations who make it possible to advance medical science by their participation. After Eli Lilly & Company market tested this public service campaign, we've learned that it not only raised awareness about the important role of trial volunteers, but when run concurrently with patient recruitment ads, inquiries and enrollment rates increased dramatically.

Public Outreach program: “AWARE for All- Clinical Research Education Day”

Aware for All is a four to six-month community outreach effort that includes: (1) a public education campaign to improve medical literacy regarding the clinical research process; (2) grassroots coalition building between health care organizations, community groups, public officials and opinion makers to address the unique dimensions of disparities in access to clinical research participation; and (3) promotion and publicity of the important contributions of clinical research volunteers.

“Education Before Participation” – educational brochures for the public

CISCRP has a growing collection of educational brochures that take complex questions about clinical research and put them into everyday language. Foremost among the materials is the Education Before Participation series, widely used today by universities, hospitals, clinical research organizations, Boards of Health, civic organizations, and community health clinics to educate people about clinical trials and the need for participation. Expanding the outreach to minority audiences, CISCRP has also developed customized versions for African Americans and Hispanics. By providing valuable information about the benefits and risks of participation, questions to ask, and places to find more information, the Education Before Participation series is a valuable tool for beginning the discussion with prospective clinical research volunteers. CISCRP also has versions in 24 languages with a country-specific list of government, disease-advocacy, and industry resources. Clinical research sites have found that these brochures ease the informed consent process.

Educational Videos

CISCRP has already developed an educational videos for the general market, as well as customized versions that are disease specific for the African American and Hispanic communities. There are videos for patients with cancer, diabetes, mental illness, breathing disorders and heart disease. These videos were produced with the help of distinguished panels of physicians and their patients. The videos were focus group tested so as to have race and cultural sensitivity and to appropriately address ethno-medical values and beliefs. The videos can be used in waiting rooms or distributed to the public/patients. Sites report that the videos ease the informed consent process and help prospective patients deal with their own families' objections to their participation in clinical trials.

¹ **Pharmaceutical and Biotechnology Update. Hogan & Hartson LLP. 27 April 2009.**