

GCRC Subject Satisfaction Survey

By Carson Reider, William Malarkey, and Haikady Nagaraja

Abstract

The Ohio State University (OSU) General Clinical Research Center (GCRC) developed a subject satisfaction survey to assess the quality of its services as perceived by study volunteers. Respondents returned 155 of 174 survey forms. Almost all respondents said they "would recommend being a GCRC research study participant to another person." Despite the very positive results, the GCRC has implemented improvements to enhance the research experience for subjects.

Introduction

Over the past decade, the national media has reported on several clinical research studies in which apparent negligence or misconduct has caused the injury or death of study subjects.¹⁻⁹ As a result, the practice of clinical research has received increased attention from the public, legislators, regulators and research institutions.¹⁰⁻¹⁶

In 2000, the National Center of Research Resources (NCRR) initiated a research subject advocacy program at its 80 General Clinical Research Centers (GCRC), located primarily at academic medical centers throughout the United States. GCRCs provide infrastructure support for government, not-for-profit, and industry-sponsored human subject research and include laboratory, nursing, nutrition, statistical and informatics services. The primary responsibility of the Research Subject Advocate (RSA) is to ensure that GCRC studies are designed, implemented and conducted safely and ethically with the protection of human subjects accorded the highest priority.

The Research Subject Advocate for the GCRC at OSU developed and conducted a satisfaction survey to assess how human subjects perceive their clinical research experience and identify opportunities for improvement.¹⁷⁻¹⁸

Methods

The OSU GCRC Administrative Assistant (Brown E) distributed 174 anonymous surveys to subjects who had completed at least one study visit at the GCRC. The survey's 20 questions were broader in scope than a previous subject satisfaction survey reported in the literature.¹⁹ Subjects were instructed to complete the surveys and to then deposit them in a drop box located at the GCRC Nursing Station. Each subject received a single copy of the survey, which was developed with assistance from GCRC Bioinformatics personnel (Lansky H and Rice B) using TELEFORM[®], a fax-based data entry system. Core Managers (Bookless H, Buck J, and Habash D) and the GCRC Program Director (Malarkey W) contributed content to the survey. Completed surveys were scanned into the TELEFORM[®] system, verified for accuracy, and exported to a Microsoft Access[®] database. A GCRC biostatistician (Nagaraja H) analyzed the responses using SAS JMP[®].

Results

Table 1 presents summary statistics of respondent demographics. Table 2 presents the results from surveys collected during the initial period of March 2003 to September 2005.

Table 1. Respondent Demographics (n=157)

Age (median)	42 years old (range 18-73)
Gender (sex)	71.3% female, 28.7% male
Race	78.5% Caucasian, 16.9% African-American, 2.6% Asian, 2.0% Native-American
Education	16.6% some high school, 28.0% high school graduates, 30.6% some college, 24.8% college grad/post graduate education

Table 2. Survey Questions and Responses (n=157)**Consent Process**

Question	Yes	No
Was the purpose of the study explained to you?	90.9%	9.1%
If yes, do you believe that you understood the purpose of the study?	100.0%	0.0%
Were the potential risks from participating in the study explained to you?	94.9%	5.1%
If yes, did you understand what those risks might be?	98.7%	1.3%
Did you feel that there was someone on the GCRC unit with whom you could discuss your questions about the procedures in the study, concerns about your participation in the study, side effects, etc.?	100.0%	0.0%
Were you given the opportunity to ask questions about the study prior to signing the consent form?	99.4%	0.6%
Would you recommend being a GCRC research study participant to others?	98.7%	1.3%

Nursing Staff

Question	Strongly Agree	Agree	Disagree	Strongly Disagree
The GCRC nurses treated me with respect	92.4%	7.6%	0.0%	0.0%
While on the GCRC, my privacy was respected.	86.6%	12.7%	0.7%	0.0%
The GCRC nurses demonstrated professionalism.	86.6%	12.7%	0.6%	0.0%
The GCRC nurses were knowledgeable about my study.	1.9%	78.3%	19.8%	0.0%
The GCRC nursing staff worked well with other members of the research team.	1.3%	86.5%	12.2%	0.0%
I am pleased with the GCRC nursing care that I received.	89.8%	9.6%	0.6%	0.0%

The GCRC nurse had the skills needed to perform the study procedures that were conducted on me.	84.1%	15.3%	0.6%	0.0%
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Environment

Question	Strongly Agree	Agree	Disagree	Strongly Disagree
I felt that the GCRC was clean.	73.8%	23.6%	0.6%	0.0%
The noise level on the GCRC was not bothersome.	74.4%	21.2%	3.8%	0.6%
I felt that the accommodations on the GCRC were comfortable.	72.7%	26.0%	1.3%	0.0%

Meals

Question	Strongly Agree	Agree	Disagree	Strongly Disagree	N/A
My meals were satisfactory.	11.9%	61.6%	24.5%	1.3%	0.7%
My meals were delivered to me on time.	13.3%	70.7%	15.3%	0.7%	0.0%

Discussion

155 of 157 respondents (98.7%) said that they would recommend being a GCRC research study participant to others. With a response rate of 90.2%, this favorable result indicates that most members of the GCRC subject population in the assessment period were satisfied with their experience.

Responses to the questions related to the consent process are encouraging. 90.9% of respondents said that the purpose of study had been explained to them. 94.9% said that the risks of the study had been explained. Respondents said that they understood the purpose and risks of the study (100% and 98.7%, respectively). Moreover, 99.4% of respondents said they had the opportunity to ask questions and 100% said that they had someone to whom they could go to for answers to their research related questions.

Various articles discuss aspects of the informed consent process, including decision-making capacity, voluntariness, disclosure, comprehension, authorization and policies.²⁰⁻²² A limitation of this survey is that it does not reveal how the respondents' self-perceived understanding relates to these components of comprehension.

Nevertheless, in the review by Flory and Emanuel, it appears that the most effective method to ensure better subject understanding of consent documents is extended person-to-person interaction.²¹ RSA activities may have promoted such additional dialogue between subjects and researchers, and contributed to the favorable responses to the surveyed aspects of consenting.

Overall, respondents said they were pleased with the nursing care that they received (99.4%). The skill and efforts of the nursing staff may have contributed to the overall favorable research experience. Most respondents said that their privacy was respected by the GCRC nurses, who demonstrated professionalism, were knowledgeable about their study, were necessarily skilled, and worked well with other members of the research team. However, 19.8% of respondents said that nurses were not knowledgeable about the study

and 12.2% said the nurses did not work well with other members of the research team. It is unclear whether these ratings reflect the actions of general GCRC staff and/or protocol-specific research staff (i.e., research nurse and/or study coordinator), because respondents may not have differentiated staff by category. Finally, more than 75% of respondents said they were satisfied with the physical environment of the GCRC and the meals that were provided. It is unknown how these responses compare to those of the larger OSU hospital. Nevertheless, attention to food quality, promptness of meal delivery, and the physical environment of the GCRC may contribute to the respondents' high level of satisfaction with their GCRC research experience.

Future Directions

OSU GCRC continues to use the survey as part of its quality improvement program. Areas that need improvement continue to be identified. For example, to improve the level of study knowledge by GCRC nurses, two lead nurses are now assigned to each study and all GCRC nurses receive in-service training for all studies. The RSA is working with study coordinators to ensure that they adequately discuss the purpose, risks and benefits of research protocols with study subjects, and reinforce their understanding that the process of informed consent is an ongoing dialogue between subjects and researchers. In the future, the RSA may participate in the consenting dialogue for selected studies that are high-risk or designated by the Institutional Review Board (e.g., gene transfer studies). Improvements in the facilities since the assessment period, which include a metabolic kitchen and additional patient space, should improve the study experience.

The survey has been revised to include questions that clarify whether the respondent is the subject or caregiver/parent/other, and that "age" refers to the subject, who may not be the person completing the survey. These clarifications will help improve services to sub-populations such as children. In the future, questions may be added concerning the incidence of and response to adverse events, inpatient vs. outpatient status, and type and quality of ancillary services (e.g., exercise physiology laboratory procedures).

It would be useful to conduct similar surveys at other GCRCs, as well as outside that network. Comparing the results may identify best practices and trouble spots.

Conclusion

GCRCs have the opportunity to serve as role models for the safe, ethical and professional conduct of clinical research. Nationally, GCRCs can collectively develop standards for the research environment, ethical conduct, and professional competency. Satisfaction surveys give the subjects a voice in this process and provide research facilities feedback from the ultimate recipient of their services – study volunteers. Moreover, given the difficulty of enrolling human subjects into clinical trials, it would be worth the effort to maximize their satisfaction with their research experience. This survey has been a step in that direction.

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