A Computer-Based Education Intervention to Enhance Surrogates' Informed Consent for Genomics Research

By Ann K. Shelton, RN, PhD, Bradley D. Freeman, MD, Anne F. Fish, RN, PhD, Jean A. Bachman, RN, DSN, and Lloyd I. Richardson, PhD

Background Many research studies conducted today in critical care have a genomics component. Patients' surrogates asked to authorize participation in genomics research for a loved one in the intensive care unit may not be prepared to make informed decisions about a patient's participation in the research.
Objectives To examine the effectiveness of a new, computer-based education module on surrogates' understanding of the process of informed consent for genomics research.
Methods A pilot study was conducted with visitors in the waiting rooms of 2 intensive care units in a Midwestern tertiary care medical center. Visitors were randomly assigned to the experimental (education module plus a sample genomics consent form; n = 65) or the control (sample genomics consent form only; n = 69) group. Participants later completed a test on informed genomics consent.
Results Understanding the process of informed consent was greater (P=.001) in the experimental group than in the control group. Specifically, compared with the control group, the experimental group had a greater understanding of 8 of 13 elements of informed consent: intended benefits of research (P=.02), definition of surrogate consenter (P=.001), withdrawal from the study (P=.001), explanation of risk (P=.002), purpose of the institutional review board (P=.001), definition of substituted judgment (P=.03), compensation for harm (P=.001), and alternative treatments (P=.004).
Conclusions Computer-based education modules may be an important addition to conventional approaches for obtaining informed consent in the intensive care unit. Preparing patients' family members who may consider serving as surrogate consenters is critical to facilitating genomics research in critical care. (*American Journal of Critical Care.* 2015;24:148-155)

doi: http://dx.doi.org/10.4037/ajcc2015983

Patients in the intensive care unit (ICU) often are unable to give informed consent because of cognitive or physical impairments due to illness, trauma, or sedation.[1,2] In such circumstances, a patient's family member or proxy is asked to serve as a surrogate and provide informed consent on behalf of the patient.[3,4] With increasing frequency, surrogates of ICU patients are being asked to provide consent for crucial genomics research.[5,6] This type of research has an immediate aspect[7,8]; any delay in consent for enrollment in the study may result in a missed opportunity to collect transient and perhaps vital clinical data.[9,10] Furthermore, genomics research is complex and has inherent ethical, legal, and social implications.[11,12] Without a basic understanding of the process of informed consent related to genomics research, surrogates may be poorly prepared to consent for their loved ones to participate in the studies.[13]

The ICU environment is challenging for a patient's surrogates because of the immediate need to react to changes in the patient's condition.[14,15] Because of these multiple stressors,[16-18] surrogates giving consent in the ICU may benefit from a focused computer-based educational intervention as an addition to conventional consent forms. However, no studies have specifically examined the effectiveness of such interventions on surrogates' understanding of informed consent for genomics research in the ICU. We found 9 high-quality studies[19-27] in which investigators examined a computer-based educational intervention and the outcome (understanding informed consent), but the researchers focused on procedures, a medical treatment, or non-ICU research and rarely used a surrogate. Computer-based educational interventions have been effective in enhancing understanding of the process of informed consent in procedural studies (cardiac catheterization, colonoscopy, endoscopy with parent as surrogate, and gastric banding surgery) and in a study on medical treatments (chemotherapy).[19-23] Additionally, 4 studies[24-27] focused on non-ICU research: 1 involved a cancer clinical trial, 1 had a sample composed of schizophrenic patients, 1 had patients' parents as surrogates in high- and low-risk clinical trials, and 1 was a genetic tissue repository study. Results were mixed. The computer-based educational interventions used in the studies included video, CD-ROM, and slide presentations, yet no single approach has been more effective than another.[26]

The purpose of this pilot study was to examine the effectiveness of a new, computer-based education module on the understanding of patients' surrogates about the process of informed consent for genomics research in the ICU. The framework of the study was the Code of Federal Regulations[28] and the principles of respect for persons, beneficence, and justice contained in the Belmont Report.[29] Specifically, within the principle of respect for persons, we focused on the need to provide full disclosure of information to surrogates who were called on to give informed consent by using substituted judgment, and to make sure the surrogates understood the information disclosed.[30,31] The term substituted judgment means that the surrogate chooses whether or not to allow a loved one to be entered into a research study on the basis of what the loved one would have wanted.[32,33] The premise is that giving surrogates information is beneficial and that subsequently giving them a test on the information will clarify how much of the disclosed information they actually understood.[34-36]

Increasingly patient surrogates are being asked to provide consent for crucial genomics research.

Methods

Design, Setting, and Sample

An experimental, posttest-only design with random assignment to group was used. The experimental group completed the computer-based education

About the Authors

Ann K. Shelton is an assistant professor, Department of Primary Care Nursing, School of Nursing, Southern Illinois University Edwardsville. **Bradley D. Freeman** is a professor, Division of General Surgery, Acute and Critical Care Surgery Section, Washington University School of Medicine, St Louis, Missouri. **Anne F. Fish** and **Jean A. Bachman** are associate professors, College of Nursing, and **Lloyd I. Richardson** is the Curator's Teaching Professor, College of Education, University of Missouri-St Louis, St Louis, Missouri.

Corresponding author: Ann K. Shelton, RN, PhD, Southern Illinois University Edwardsville, Box 1066, 2335a Alumni Hall, Edwardsville, IL 62026-1066 (e-mail: ashelto@siue.edu).

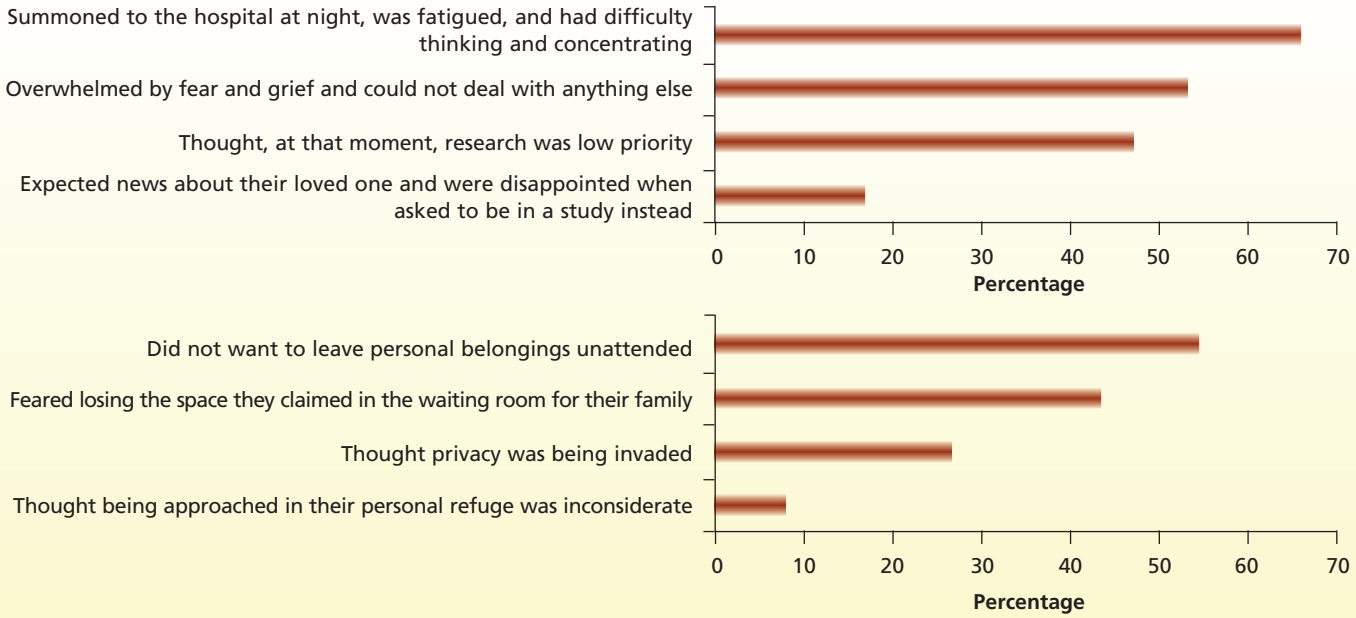

Figure Reasons for nonenrollment in the study given by visitors in the waiting rooms of the intensive care units. Top, Dealing with issues of uncertainty about their loved one. Bottom, Dealing with the environment in the waiting room. The percentages are greater than 100 because visitors had more than 1 reason for declining to participate.

module and received a sample genomics consent form; the control group received the sample genomics consent form only. The setting was the waiting rooms of 2 ICUs (surgical-trauma and cardiac) in a Midwestern tertiary care medical center.

The participants in the study were adult visitors to the ICU waiting rooms. All of the visitors were considered potential surrogate consenters in the future and therefore were the surrogates for the purpose of this study. Persons were eligible for the study if they were visitors to the ICU waiting rooms, were 18 years or older, and were willing to participate in the study. Visitors were approached unless they appeared to be in crisis or actively grieving. A power analysis indicated that a total of 64 participants was needed per group to detect a 0.50 effect with a power of 0.80 and $\alpha = .05$.

The sample included only those individuals who felt comfortable participating at that time.

During a 4-month period, 827 visitors were approached for the study; of these, 137 agreed to participate in the study. The Figure presents reasons for nonenrollment in the study. Visitors who declined did not have reservations about the study itself; they had personal reasons for not enrolling. Their responses fell into 2 general categories: dealing with the uncertainly related to their loved ones in the ICU and dealing with the ICU environment. The conclusion was that the sample was not biased in any way because it included only those visitors who felt comfortable participating at the time of recruitment.

Computer-Based Education Module

The education module was presented on a laptop computer and included a series of 36 slides. It was developed by a nurse researcher and was based on the Code of Federal Regulations and on related publications[37,38] about the ethical, legal, and social implications for genomics research. An expert panel of 15 ICU physicians approved the content of the slides. The panel included 2 experts who were conducting research on informed consent. The information was written at or below the sixth grade level of reading comprehension. The brightly colored slides were designed to include persons of multicultural backgrounds. In addition, 4 slides had animated material to enhance interest.

The module included an introduction, educational content, and a summary. The educational content included information about the 13 essential elements of informed consent[28,29] (Table 1), surrogate consent,[2,4] research in general,[24,25] and genomics research.[8,12] The slides specific to surrogate consent included information on the definition of a surrogate,[1,3] definition of substituted judgment,[31,33] and requirement that the researcher must provide all of the information that the surrogate needs to make an informed decision about participation in the research.[1] The slides on research in general included information about research in the ICU, reasons for participating in research, role of the institutional review board, and who pays for research.[1,4] The slides on genomics research included information on the definition of genomics,[7] interactions between genes

and the environment,[11] meaning and implications of DNA,[12] and ownership of tissue specimens.[39] Finally, 1 slide summarized the elements of informed consent.[28,29] The module was pretested with 7 adults.

Sample Genomics Consent Form

The sample genomics consent form was a 7-page form printed on white paper. The information was written at or below the sixth grade level of reading comprehension. The consent form had been approved by the institutional review board, was about ventilator-associated pneumonia in the ICU, and had been used in a recent genomics study at the research site. In content detail, overall structure, and format, it was representative of a typical consent form for genomics research used at the study site. This consent form was used as a sample only, and participants were clearly instructed that their loved ones were not being recruited for a study on ventilator-associated pneumonia.

Instrument

The posttest instrument was a 13-item instrument with a 5-point Likert-type response format (1 = definitely false and 5 = definitely true). The posttest was used to measure surrogates' understanding of the process of informed consent. Items on the instrument reflected essential elements of informed consent that the literature had indicated as necessary for surrogates to understand (Table 1). Higher scores indicated greater understanding of the process of informed consent. Content validity was established through the use of a content analysis table and examination by a panel of experts who evaluated the posttest according to the Code of Federal Regulations guidelines and publications on informed consent.[28,29] The Cronbach α of the posttest was 0.73.

Data Collection Procedures

The study, approved by the appropriate institutional review board, was carried out in accordance with the ethical standards set forth in the Helsinki Declaration of 1975,[38] and was conducted by 1 nurse researcher. The visitors were studied individually; visitors who were together with other family members were asked not to share information about the study. A private consultation room within the ICU waiting room was used to ensure a quiet space for the study. After entering the study room, visitors were randomly assigned to a group by using computer-generated random numbers. Participants read an information sheet written at or below the sixth grade level of reading comprehension, which explained the purpose of the study. Any questions participants had were answered. Participants in the experimental group were shown how to advance the slides on the laptop. The experimental group completed the computer-based education module and then read the sample genomics consent form. The control group read the sample genomics consent form only. Both groups completed the posttest and the demographic data form. A posttest key was given to all participants to check their answers. After each participant completed the posttest, the researcher again solicited and answered questions. Additionally, the researcher provided participants contact information in case they had further questions. Visits did not exceed 30 minutes. Visitors received no remuneration for their participation.

Table 1
Essential elements of informed consent[a]

1. Intended benefit for future patients
2. Purpose of surrogate consenting
3. Study withdrawal
4. Purpose and length of the study
5. Overall research risks
6. Purpose of the institutional review board
7. Need for and purpose of researcher's contact information
8. Sufficient information to make an informed decision
9. The voluntary nature of research
10. Substituted judgment
11. Confidentiality of information
12. Compensation for harm
13. Alternative treatment

[a] Based on the Code of Federal Regulations,[28] the Belmont Report,[29] and other published material.

> The posttest measured surrogates' understanding of the informed consent process.

Data Analysis

Descriptive statistics, χ^2 analysis, the Fisher exact test, and independent *t* tests were used to summarize demographic data. According to the self-reports of the participants' relationship to the ICU patients, the loved one was a spouse, fiancée, significant other, parent, sibling, child, friend, or other. Analysis of variance was used to analyze overall total posttest scores. Multivariate analysis of variance was used to determine between-group differences among the items. Top-box statistics were used to describe the percentage of participants who chose the most correct answers (probably true or definitely true) for each posttest item.

Table 2
Demographic characteristics according to group[a]

Variable	No. (%) of particiants		P
	Experimental (n = 65)	Control (n = 69)	
Sex			.50
Male	20 (31)	25 (36)	
Female	45 (69)	44 (64)	
Race			.76
African American	15 (23)	18 (26)	
White	50 (77)	50 (72)	
Hispanic	0 (0)	1 (1)	
Education			.63
Less than high school	2 (3)	1 (1)	
High school graduate	15 (23)	19 (28)	
Some college	23 (35)	24 (35)	
College graduate	22 (34)	18 (26)	
Postgraduate college	3 (5)	7 (10)	
Experience participating in a previous research project	5 (8)	6 (9)	.68
Relationship to patient[b]			
Spouse	10 (15)	10 (14)	
Fiancée	0 (0)	3 (4)	
Significant other	1 (2)	2 (3)	
Parent	13 (20)	7 (10)	
Sibling	5 (8)	13 (19)	
Child	12 (18)	13 (19)	
Friend	2 (3)	2 (3)	
Other	22 (34)	19 (28)	

[a] Because of rounding, not all percentages total 100.
[b] Because of low numbers in the relationship categories, no statistical tests were performed.

Results

Characteristics of the Sample

Of the 137 participants, 3 were called away during the session and did not complete the study, leaving a total of 134 visitors in the sample. A total of 65 participants in the experimental group and 69 in the control group completed the study. Participants were 19 to 82 years. The mean age was 49.4 (SD, 15.35) years for the experimental group and 45 (SD, 15.53) years for the control group. Demographic variables did not differ significantly between the 2 groups (Table 2).

Effectiveness of the Education Module

Overall, the experimental group had a greater ($P = .001$) understanding of the process of informed consent than did the control group. Age, sex, race, education, and previous experience participating in a research project did not significantly influence this finding.

Furthermore, according to the top-box statistic, the percentage of participants who picked the most correct responses (probably true and definitely true) was higher in the experimental than in the control group (Table 3). Specifically, compared with the control group, the experimental group had greater understanding of 8 of 13 elements of informed consent: intended benefits of research ($P = .02$), definition of surrogate consenter ($P = .001$), study withdrawal ($P = .001$), explanation of risk ($P = .002$), purpose of the institutional review board ($P = .001$), definition of substituted judgment ($P = .03$), compensation for harm ($P = .001$), and alternative treatments ($P = .004$).[3,28,29]

The 2 groups did not differ significantly for 4 posttest items: the right to know the purpose and duration of the study, the provision of researcher contact information in the event of questions, the voluntary nature of the research, and the confidentiality of information (Table 3). This finding indicates that, if the sample genomics consent form fully covered these items, additional information on these topics provided in the computer-based education module did not significantly improve posttest scores.

The final item that did not differ significantly between the 2 groups was the following: the researcher must give all information needed to make an informed decision about research (Table 3). Information about this item was explicitly stated in words in the computer-based education module but was not addressed in the sample genomics consent form. Both groups of participants had high mean scores on this item, indicating that those in the control group might have had this information as general knowledge or that the item sounded true, so the scores were high.

Discussion

Our study indicated that the computer-based education module was effective in improving surrogates' understanding of the process of informed consent for genomics research in the ICU. Our findings are in general agreement with those of Bickmore et al,[27] who used a computer-based education module and a sample research consent form on genetics research. Their study and ours differ, however: the study by Bickmore et al had a smaller sample size, was not conducted in an ICU, and did not include use of surrogates.

Care should be taken when approaching possible surrogates in the ICU waiting room for the purpose of obtaining informed consent. Although research participation is important to the researcher, a request to participate in a study may be perceived by surrogates as another demand on their time. An important premise emerged from our study: A balance must exist between the mandate to conduct

Table 3
Posttest scores for understanding the process of informed consent according to group

Posttest item[a]	Experimental (n = 65)			Control (n = 69)			*P*
	Mean	SD	Top box %	Mean	SD	Top box %	
1. Research is intended to benefit patients in the future. It may not help your loved one.	4.7	0.74	74	4.2	1.18	55	.01
2. A loved one may be too ill to agree to participate in research. When that happens, you may be asked to give permission for your loved one.	4.8	0.53	68	3.7	1.36	35	.001
3. If you agree to participate in research, you may not withdraw from the study until it is finished.	4.9	0.56	86	4.4	1.25	38	.01
4. You have the right to know the purpose of the study and how long it will last.	4.7	0.76	95	4.6	0.84	75	.47
5. Research risks your loved one might face must be explained to you.	4.9	0.27	85	4.7	0.90	78	.03
6. The institutional review board approves research. Part of their job is to help protect research participants.	4.7	0.63	92	4.2	0.97	84	.001
7. The researchers will make sure you know how to contact them if you wish to ask more questions.	4.9	0.45	80	4.7	0.57	54	.09
8. The researcher must give you all the information you need to make an informed decision about research.	4.9	0.45	91	4.8	0.55	77	.16
9. Participating in research is voluntary.	5.0	0.28	91	4.9	0.29	80	.81
10. You should decide whether to allow a loved one to participate in research on the basis of what your loved one would want.	4.7	0.61	97	4.1	1.17	96	.001
11. You have the right to know if the researcher plans to keep your loved one's personal information confidential.	4.9	0.27	78	4.9	0.34	48	.32
12. The process of informed consent includes providing information about compensation for harm that may come to your loved one during research.	4.6	0.89	92	4.1	1.34	87	.01
13. Some research involves a treatment. You must be told if there are other treatments you may choose instead.	4.6	0.98	80	4.0	1.22	58	.001

[a] Item 3 is reverse coded.

genomics research and human research protections. The research mandate should not interfere with principles of respect for persons, beneficence, and justice; the inherent right of the surrogate to disclosure of all information needed and to an understanding of the information disclosed; and the opportunity of the surrogate to give voluntary and informed consent.[30]

The computer-based education module was designed with basic features to enhance surrogates' understanding of the process of informed consent, be comprehensive, and provide a single straightforward message: the importance of reviewing and understanding essential elements of informed consent before signing a consent form for a loved one to participate in genomics research in the ICU. A strength of the computer-based approach is that participants found the laptop easy to use; they had to master only a single skill: advancing the slides by using a button on the keyboard. Also, the quality of the education module was high, as judged initially by a panel of experts and then by the researcher collecting data, who noted that the module was used by participants without hesitation or questions.

With further testing, the computer-based education module might be tailored to a specific population of participants, such as those with low reading skills; be revised to include hyperlinks to provide additional information; and be produced in Spanish or other languages. Also the intervention might be used in a kiosk with new touch-pad technologies, permanently affixed in the ICU waiting room for convenient viewing by surrogates, to serve as an adjunct to brochures about the research that would also be available in the waiting room. Visitors could view the education module, read the research brochure, and then call the research nurse if they were interested in learning more about research participation

for their loved ones. However, before this approach is used clinically, additional research is needed to determine the feasibility and effectiveness of this type of kiosk in ICU waiting rooms.

A posttest-only experimental design was used because pretesting might have resulted in an unwanted sensitization effect in which the pretest itself influenced the posttest answers. Also a pretest would have taken additional time, and we purposely designed the study to limit the research visit to 30 minutes, so it would not be too much of a burden on the participants, who were already dealing with complex issues related to the illness of their loved one. A lack of a pretest might be a problem when the random assignment does not work and the 2 groups are not equivalent at baseline. A lack of a pretest also can become a problem when attrition is high. We did not expect and did not experience high attrition.

The module might be used in a kiosk with new touch pad technologies, permanently affixed in the intensive care unit waiting room.

Other limitations also were identified. First, the use of only 2 ICU waiting rooms at a single medical center might limit the generalizability of the results. Second, we do not know the extent to which the presence of transitory personal factors of participants, such as fatigue, hunger, mood, fear, and anxiety, might have led to errors in measurement. Third, the number of participants in the relationship categories was too small to be correlated with understanding the process of informed consent. That analysis should be conducted in a larger study on informed consent of surrogates in the future. Finally, this study was the first time the posttest was used, although the test's internal consistency reliability was acceptable for a new instrument.[40]

Conclusion

Computer-based education may be an important addition to conventional approaches for obtaining informed consent in the ICU. Preparing patients' family members who may consider serving as surrogate consenters is critical. Further research is needed to examine the multiple challenges that researchers and surrogates face when considering informed consent for genomics research in the ICU.

ACKNOWLEDGMENTS
This research was performed at the University of Missouri-St Louis and Washington University. We gratefully acknowledge the editorial assistance of Kathy Neff, MA.

FINANCIAL DISCLOSURES
None reported.

eLetters
Now that you've read the article, create or contribute to an online discussion on this topic. Visit **www.ajcconline.org** and click "Responses" in the second column of either the full-text or PDF view of the article.

REFERENCES

1. Luce JM, Cook DJ, Martin TR, et al; American Thoracic Society. The ethical conduct of clinical research involving critically ill patients in the United States and Canada: principles and recommendations [published correction appears in *Am J Respir Crit Care Med.* 2005;172(6);787]. *Am J Respir Crit Care Med.* 2004;170(12):1375-1384.
2. Arnold RM, Kellum J. Moral justifications for surrogate decision making in the intensive care unit: implications and limitations. *Crit Care Med.* 2003;31(5)(suppl):S347-S353.
3. Bein PM. Surrogate consent and the incompetent experimental subject. *Food Drug Cosmet Law J.* 1991;46(5):739-771.
4. Coppolino M, Ackerson L. Do surrogate decision makers provide accurate consent for intensive care research? *Chest.* 2001;119(2):603-612.
5. Cobb JP, O'Keefe GE. Injury research in the genomic era. *Lancet.* 2004;363(9426):2076-2083.
6. Luce JM. Research ethics and consent in the intensive care unit. *Curr Opin Crit Care.* 2003;9(6):540-544.
7. Freeman BD, Kennedy CR, Bolcic-Jankovic D, et al. Considerations in the construction of an instrument to assess attitudes regarding critical illness gene variation research. *J Empir Res Hum Res Ethics.* 2012;7(1):58-70.
8. Freeman BD, Kennedy CR, Frankel HL, et al. Ethical considerations in the collection of genetic data from critically ill patients: what do published studies reveal about potential directions for empirical ethics research? *Pharmacogenomics J.* 2010;10(2):77-85.
9. Harvey SE, Elbourne D, Ashcroft J, Jones CM, Rowan K. Informed consent in clinical trials in critical care: experience from the PAC-Man study. *Intensive Care Med.* 2006; 32(12):2020-2025.
10. Luce JM. Informed consent for clinical research involving patients with chest disease in the United States. *Chest.* 2009; 135(4):1061-1068.
11. Collins FS, Green ED, Guttmacher AE, Guyer MS. A vision for the future of genomics research. *Nature.* 2003;422(6934): 835-847.
12. Collins F. The threat of genetic discrimination to the promise of personalized medicine. Testimony Before the Subcommittee on Health, Committee on Energy and Commerce, US House of Representatives hearing on HR 493, the Genetic Information Nondiscrimination Act of 2007. http://www.genome.gov/10001350. Accessed January 5, 2015.
13. Azoulay E, Pochard F, Kentish-Barnes N, et al; FAMIREA Study Group. Risk of post-traumatic stress symptoms in family members of intensive care unit patients. *Am J Respir Crit Care Med.* 2005;171(9):987-994.
14. Bigatello LM, George E, Hurford WE. Ethical considerations for research in critically ill patients. *Crit Care Med.* 2003;31(3) (suppl):S178-S181.
15. Freeman BD, Kennedy CR, Coopersmith CM, Zehnbauer BA, Buchman TG. Genetic research and testing in critical care: surrogates' perspective. *Crit Care Med.* 2006;34(4):986-994.
16. McAdam JL, Puntillo K. Symptoms experienced by family members of patients in intensive care units. *Am J Crit Care.* 2009;18(3):200-209.
17. McAdam JL, Fontaine DK., White DB, Dracup KA, Puntillo KA. Psychological symptoms of family members of high-risk intensive care unit patients. *Am J Crit Care.* 2012;21(6):386-393.
18. Jones C, Skirrow P, Griffiths RD, et al. Post-traumatic stress disorder-related symptoms in relatives of patients following intensive care. *Intensive Care Med.* 2004;30(3):456-460.
19. Tait AR, Voepel-Lewis T, Moscucci M, Brennan-Martinez CM, Levine R. Patient comprehension of an interactive, computer-based information program for cardiac catheterization:

a comparison with standard information. *Arch Intern Med.* 2009;169(20):1907-1914.
20. Shaw MJ, Beebe TJ, Tomshine PA, Adlis SA, Cass OW. A randomized, controlled trial of interactive, multimedia software for patient colonoscopy education. *J Clin Gastroenterol.* 2001;32(2):142-147.
21. Friedlander JA, Loeben GS, Finnegan PK, et al. A novel method to enhance informed consent: a prospective and randomised trial of form-based versus electronic assisted informed consent in paediatric endoscopy. *J Med Ethics.* 2011;37(4):194-200.
22. Eggers C, Obliers R, Koerfer A, et al. A multimedia tool for the informed consent of patients prior to gastric banding. *Obesity.* 2007;15(11):2866-2873.
23. Olver IN, Whitford HS, Denson LA, Peterson MJ, Olver SI. Improving informed consent to chemotherapy: a randomized controlled trial of written information versus an interactive multimedia CD-ROM. *Patient Educ Couns.* 2009;74(2):197-204.
24. Hoffner B, Bauer-Wu S, Hitchcock-Bryan S, Powell M, Wolanski A, Joffe S. "Entering a Clinical Trial: Is It Right for You?": a randomized study of The Clinical Trials Video and its impact on the informed consent process. *Cancer.* 2012; 118(7):1877-1883.
25. Dunn LB, Lindamer LA, Palmer BW, Schneiderman LJ, Jeste DV. Enhancing comprehension of consent for research in older patients with psychosis: a randomized study of a novel consent procedure. *Am J Psychiatry.* 2001;158(11):1911-1913.
26. Campbell FA, Goldman BD, Boccia ML, Skinner M. The effect of format modifications and reading comprehension on recall of informed consent information by low-income parents: a comparison of print, video, and computer-based presentations. *Patient Educ Couns.* 2004;53(2):205-216.
27. Bickmore TW, Pfeifer LM, Paasche-Orlow MK. Using computer agents to explain medical documents to patients with low health literacy. *Patient Educ Couns.* 2009;75(3):315-320.
28. Code of Federal Regulations, Title 45, Public Welfare, Department of Health and Human Services, Part 46, Protection of Human Subjects. http://www.hhs.gov/ohrp/humansubjects /guidance/45cfr46.html. Revised January 15, 2009. Accessed December 3, 2014.
29. US Department of Health, Education, and Welfare, National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The Belmont report: ethical principles and guidelines for the protection of human subjects of research. http://www.hhs.gov/ ohrp/humansubjects /guidance/belmont.html. Published April 18, 1979. Accessed December 3, 2014.
30. Henry J, Palmer BW, Palinkas L, Glorioso DK, Caligiuri MP, Jeste DV. Reformed consent: adapting to new media and research participant preferences. *IRB.* 2009;31(2):1-8.
31. Burns KE, Zubrinich C, Marshall J, Cook D. The "Consent to Research" paradigm in critical care: challenges and potential solutions. *Intensive Care Med.* 2009;35(10):1655-1658.
32. Burns EA, Magyarody NM, Duffett M, Nisenbaum R, Cook DJ. Attitudes of the general public toward alternative consent models. *Am J Crit Care.* 2011;20(1):75-83.
33. Torke AM, Alexander GC, Lantos J. Substituted judgment: the limitations of autonomy in surrogate decision making. *J Gen Intern Med.* 2008;23(9):1514-1517.
34. Cohn E, Larson E. Improving participant comprehension in the informed consent process. *J Nurs Scholarsh.* 2007;39(3): 273-280.
35. Flory J, Emanuel E. Interventions to improve research participants' understanding in informed consent for research: a systematic review. *JAMA.* 2004;292(13):1593-1601.
36. Schenker Y, Fernandez A, Sudore R, Schillinger D. Interventions to improve patient comprehension in informed consent for medical and surgical procedures: a systematic review. *Med Decis Making.* 2011;31(1):151-173.
37. Jeffers BR. Human biological material in research: ethical issues and the role of stewardship in minimizing research risks. *ANS Adv Nurs Sci.* 2001;24(2):32-46.
38. Huang DT, Hadian M. Bench-to-bedside review: human subjects research—are more standards needed? *Crit Care.* 2006;10(6):244.
39. O'Doherty KC, Hawkins AK, Burgess MM. Involving citizens in the ethics of biobank research: informing institutional policy through structured public deliberation. *Soc Sci Med.* 2012;75(9):1604-1611.
40. Kline P. *The Handbook of Psychological Testing.* 2nd ed. New York, NY: Routledge; 2000.