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Long-Term Recall of Elements of Informed Consent: A Pilot Study Comparing Traditional and Computer-Based Consenting

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Abstract

Background: The purpose of this study was to evaluate long-term recall of elements of informed consent.

Methods: Men enrolling in a biobank for a study of prostate cancer were randomized to traditional or computer-based consenting. Two-page questionnaires were mailed to participants six months after the consent process.

Results: Thirty-five men were randomized to the computer-based arm and 36 to the traditional consenting arm. Follow-up questionnaires were returned by 25 in the computer-based and 31 in the traditional group. The men ranged in age from 55 to 86 years (mean 73.2). Participants in the computer-based group were more likely to answer some of the knowledge questions correctly. The computer-based respondents were more likely to report higher levels of understanding for 13 of 14 statements.

Discussion: The computer-based consenting process decreased staff time required and lead to improved retention of the elements of informed consent. It has been adopted prospectively.

Keywords

computer-based; informed consent; knowledge

The number of biobanks is increasing globally to develop the infrastructure to support large-scale biological discoveries for personalized medicine. Consent forms and processes have been proposed for biobanks[1–2] with no discussion about the most effective means to provide the information to potential biobank subjects to enhance their knowledge and understanding to make truly informed decisions about participation. A review of interventions to improve research participant's understanding of the informed consent process found that the use of multimedia and enhanced consent forms had only limited success[3] while the authors of a Cochrane Review concluded that the value of audio-visual interventions for people

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considering participation in clinical trials is unclear and further research is needed[4]. In a randomized controlled study of computer-based presentation versus traditional paper-based information for a mock study in adults with diabetes, assessment scores were found to be significantly higher in the computer-based group[5]. In a randomized clinical trial of a computer-based decision aid versus standard one-on-one genetic counseling about genetic testing for breast cancer susceptibility, the interactive computer program was associated with increased knowledge of breast cancer and genetic testing in women at low risk of carrying a genetic mutation for breast cancer[6].

The Personalized Medicine Research Project is a population-based biorepository in central Wisconsin[7]. We have shown previously that recall of some of the key elements of informed consent was low[8]. We responded to these findings by providing information about the study in newsletters mailed to previously enrolled subjects[9–10], by emphasizing the areas that were shown to be frequently forgotten when prospectively enrolling participants, and by developing a computer-based consenting process with built-in questions. The purpose of this study was to evaluate computer-based consenting versus traditional consenting for participation in a population-based biobank in a randomized clinical trial to assess long-term recall of specific items in the informed consent process.

Methods

Recruitment

Participants for the current study were enrolled in the Marshfield Clinic Personalized Medicine Research Project (PMRP), a population-based biobank in central Wisconsin. Details of the biobank methodology have been published previously[7]. Enrollment involved the completion of several questionnaires about personal exposures and a blood draw from which DNA was extracted and DNA, plasma and serum samples were stored. Participants were offered $20 to cover any expenses, such as gas, to participate.

Targeted recruitment into PMRP for a specific study was taking place at the time of this consenting process evaluation sub-study. Men aged 55 and older with prostate cancer were specifically being invited to participate in PMRP. The usual biobank recruitment letter was modified to indicate that a study of prostate cancer was being conducted within the biobank and that they had been identified because of a prostate cancer diagnosis to enroll in the biobank. The recruitment letters were followed by telephone calls from a Research Coordinator to explain the biobank, answer questions, invite participation and schedule a consenting/enrollment appointment if interested.

The institutional review boards at Marshfield Clinic and Essentia Health reviewed and approved the biobank and current study of consenting. All subjects signed the informed consent document prior to enrollment.

Consent form and process

The original PMRP written informed consent document was modified to lower the reading level from 12.1 to 8.0 and to add language about dbGaP (the National Library of Medicine database that houses phenotype and GWAS data), access to stored pathology samples for

future research and the potential to access residual clinical blood samples. A script was developed for a computer-based consenting process and then filmed with one of the investigators (CAM) as the moderator. Seven knowledge questions were imbedded within the consenting program to evaluate comprehension of key concepts that were identified in the previous survey of enrollees as problem areas (Table 1). A kiosk with a touch screen was used to display the consenting program and subsequently made available on laptop computers. Hot links allowed subjects to go to exact sections of the written informed consent document and to access further information on topics. Closed captioning and headphones were available as needed.

The consent form was mailed out to potential participants along with their appointment reminders so that they had the opportunity to review it prior to their appointment. However, anecdotally few people read the written document before their enrollment appointment. In the traditional consenting process, trained Research Coordinators reviewed the written informed consent document with potential subjects, highlighting key elements on each page and checking for comprehension by asking potential subjects if they understood the document or had any questions. Any questions that the Research Coordinator could not answer were referred to the Principal Investigator.

At the biobank consenting/enrollment visit, the men were asked if they would be willing to be enrolled in the sub-study to evaluate the informed consent process. If they agreed, they were randomized to either the traditional consenting process or the computer-based consenting process. Men randomized to the computer-based group signed their consent forms electronically. They were not asked to sign separate consent forms for the evaluation of the consenting process, nor did they sign separate consent forms for the biobank by virtue of the fact that they had been specifically recruited because of previous diagnosis of prostate cancer. The biobank consent form mentions studies of specific diseases within the biobank.

Study instruments and analyses

All subjects were mailed a two-page self-administered questionnaire approximately six months after PMRP enrollment. The same questionnaire was employed in an earlier project in the PMRP cohort[8]. It was adapted from a questionnaire originally validated for use in cancer clinical trial participants[11] and subsequently used for biobank participants at Northwestern University[12]. The questionnaire included 24 statements primarily related to knowledge of the elements of informed consent and 14 statements for which subjects were asked to indicate their level of understanding on a five-point scale. A question was also included about the extent to which the $20 to cover any expenses related to enrollment influenced their decision to participate. Comparisons were made between the traditional and computer-based and between the current and historical cohorts using Wilcoxan and Fisher's exact tests. Comparisons were made with the study conducted five years earlier to ascertain any temporal changes that may have occurred as a result of ongoing community education and engagement activities about the biobank that may have led to higher comprehension scores because of increased general knowledge in the lay community about genomic research. SAS® (Cary, North Carolina) was used for statistical analyses and p-value <0.05 was considered to be statistically significant. Sample size calculations were not done prior to

study initiation. The intention was to attempt to recruit all men enrolling in the biobank who were being recruited because of a prior history of prostate cancer.

Results

Recruitment and follow-up

One-hundred twenty-two men who were enrolling in the PMRP biobank were approached to participate in the consenting study; 71 (58%) agreed - 35 were randomized to the CBT and 36 to traditional consent. The majority of the 52 men who participated in the biobank but declined participation in the consent study cited the reason “not interested”. Two people declined participation in the consent study because they did not want to be randomized to the kiosk; they preferred the face-to-face consent process. Two people withdrew from the computer-based consenting arm after they had started and changed to traditional consent; one changed his mind about being willing to use the computer and one was unable to hear even with use of the headphones. They were not followed further for the consenting study. The men who were randomized to the computer-based consenting reported that the program was easy to use.

Six-month follow-up questionnaires were returned by 25 (76%) of the computer-based group and 31 (86%) of the traditional consenting group. The subjects ranged in age from 55 to 86 years, mean 73.2. The mean duration of time for the consenting process for the CBT group was 19.0 minutes (SD 2.0) and for the traditional consenting group was 16.4 minutes (SD 3.1). This difference was statistically significant (Wilcoxan p-value<0.001).

The computer-based group answered all of the imbedded questions correctly except question three, the question related to direct benefit for enrolling in the study. Three men agreed with that statement because they perceived the $20 as direct benefit.

Comparison between current and historical cohorts

Comparisons of responses to factual statements related to the elements of informed consent between the current and previous cohorts in relation to level of understanding of various components of the PMRP are summarized in Table 2. For all but two of the statements, current participants were less likely to indicate that they were unsure of an answer than the previous cohort, suggesting a temporal change in general community knowledge related to genomic research.

Comparisons of the current and previous cohorts in relation to level of understanding of various components of the PMRP are summarized in Table 3. Respondents indicated higher levels of understanding in the current study in comparison with the study conducted approximately eight years earlier for all statements except the first two which related to understanding of what was being studied.

Comparison between computer-based and traditional consenting

The distribution of responses to the factual and level of understanding statements was quite similar between the computer-based and traditional consent groups with the exception of two statements that differed significantly between the two groups (Tables 4 and 5). The

computer-based group was more likely to accurately disagree with the statement that genetic testing would result in the learning what conditions they might develop (48% vs. 26%, p=0.045). The computer-based group was also more likely to disagree with the statement that researchers offered any alternatives to involvement in the research study (64% vs. 32%, p=0.013).

Understanding of who would pay for treatment if someone was injured or became ill as a result of participating in the PMRP was also remarkably different between the two randomization groups (p=0.78).

Most people either incorrectly answered question #4 about all the procedures being standard for any routine genetic testing or were unsure of their answer. This was true at both time points and for both randomization groups in the current study, indicating that the question may have been poorly phrased.

Discussion

To our knowledge, this is the first report of a computer-based consenting process for prospective enrollees in a biorepository. The tool used to evaluate understanding of the elements of informed content was used previously to assess understanding of the PMRP biobank[8] and biobank participants at Northwestern University[12]. In the Northwestern study, three of the knowledge questions were answered incorrectly by more than half the participants: 1) one of the major goals is to explore genetic basis for reactions to prescription drugs (40.5% correctly agreed), 2) it is possible that people not directly involved with the study could have access to my medical records (34.7% correctly agreed), and 3) the consent form describes who will pay for my treatment if I am injured (18.6% correctly agreed)[12]. Improvements were seen in the correct responses to these questions in the PMRP cohort between the two times that the questionnaire was administered and more than half of the computer-based consenting group correctly answered these questions.

There are different interpretations of therapeutic misconception[13] and therapeutic optimism[14] in the literature. In the context of a biobank rather than a clinical trial, therapeutic misconception and therapeutic optimism may result from a lack of understanding of the scientific process and timeline for translation of research results into clinical care. Nearly 1/3 of subjects in the current study were unsure whether they would learn about conditions/diseases they might develop as a result of participation in the biobank. A study of research participants in a genetic epidemiology study in the U.K. found that 28% of participants incorrectly thought that genetic results would be returned to them and 41% thought that research findings related to the study would benefit themselves or their family in the future[15]. It is not known to what extent this misunderstanding motivated participant's decisions to participate in the study nor is that known for the PMRP. Another possible factor leading to therapeutic misconception in the context of biobank consent is hope. Indeed, members of the PMRP Community Advisory Group and focus group participants have indicated that they participated because they are hopeful that their participation will make a difference to future medical care for themselves and others[9–10].

In comparison with our previous study where 2% of subjects felt pressured by someone other than PMRP personnel to participate in the project[8], no one in the current study agreed with that statement. This could reflect the older mean age of 73 years in the current cohort in comparison to the mean age of 49 years in the original cohort. Interestingly, when the entire PMRP cohort was contacted in 2009, a few people withdrew citing the reason that they initially felt coerced by a family member to participate[10]. The current cohort was significantly less likely to feel that the $20 greatly influenced their decision to participate in the PMRP which may reflect the fact they had been diagnosed with a disease (prostate cancer) which was being studied and they therefore felt motivated to participate to help others with their disease in the future as opposed to the more general community-based approach to recruitment previously.

Several study limitations must be acknowledged. First, the study population included only older men, therefore the results may not be generalizable to other potential biobank participants. Second, the initial response to the request to participate in the consenting process sub-study was rather low (58%). The primary reason given when declining to participate (not interested) provides little insight for future study or implementation. It is possible that the computer-based consenting process was intimidating for the older men and that perhaps younger people would be more receptive to the computer technology. Finally, the relatively small sample size resulted in many non-significant results.

Computer-based consenting decreased staff time required for face-to-face consenting and lead to improved retention of the elements of informed consent. It was well accepted and has been adopted for use prospectively for PMRP biobank enrollment, despite the fact that many of the observed results were not statistically significant. One of the reasons for adoption of the computer-based consenting process based on the results presented in this paper was feedback from the PMRP Community Advisory Group. They were involved with the development of the tool and have been adamant that limited research resources be used for research that will make difference to health care in the long run. Also, the traditional consenting process continues to be offered to people who are not comfortable with computers or have difficulty with the kiosk. We will continue to gather qualitative feedback from biobank participants about the computer-based consenting process and update as necessary. Future research may involve the implementation and evaluation of an informed consent process through the internet in addition to the stationery kiosks and laptop computers currently in use.

In conclusion, the computer-based consenting process, developed in consultation with a Community Advisory Group, provides an alternative to traditional face-to-face consenting that resulted in improved long-term recall of the elements of informed consent. By offering alternative options for the consenting process we hope to improve understanding so that all study subjects make truly informed decisions about study participation. This approach may be useful for other study types, in other study populations and for clinical consenting.

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Table 1.

Imbedded knowledge questions in computer-based consenting module

Question	Possible responses (correct response highlighted in bold)
1. A goal of the project is to predict the development of disease. Another goal is to learn how we respond to medication.	**True** False
2. How long will you be in the research study?	A. Until 2010 B. Until 2020 **C. There is no planned end date**.
3. There will be no direct benefit for enrolling in the project.	**True** False
4. We will use information from your medical record, medical samples and stored DNA.	**True** False
5. How will your confidentiality be protected under the Personalized Medicine Research Project?	A. We will follow the HIPAA privacy rule, which requires us to keep your medical information private. B. We will not put your genetic results into your medical record. C. All information is coded when it's entered in the database. **D. All of the above**.
6. We may share some of your samples or information with other researchers or institutions to further medical research.	**True** False
7. After you have been enrolled in the project, can you withdraw from this project if you wish to do so?	A. No B. Yes, after 5 years **C. Yes, at any time**

Table 2.

Comparison between current (line 1 in each row) and previous (line 2 in each row) cohorts about factual statements related to informed consent. Expected responses are highlighted in bold.

Statement	Agree	Disagree	Unsure	p-value
1. When I signed the consent form to have my blood drawn, I knew that I was agreeing to participate in a research project.	52 (100%) 915 (99.1%)	0 (0%) 0 (0%)	0 (0%) 8 (0.9%)	1.000
2. The main goal of genetic research studies, such as the Personalized Medicine Research Project, is to improve scientific knowledge for future patients.	52 (100%) 904 (98%)	0 (0%) 2 (0.2%)	0 (0%) 16 (1.7%)	1.000
3. I have been informed how long my participation in the Personalized Medicine Research Project is likely to last.	34 (68.0%) 532 (57.8%)	0 (0%) 21 (2.3%)	16 (32.0%) 367 (39.9%)	0.328
4. All the procedures in the research project are standard for any routine genetic testing.	44 (84.6%) 604 (65.9%)	0 (0%) 7 (0.8%)	8 (15.4%) 306 (33.4%)	0.018
5. In this research project, one of the major goals is to understand how genes contribute to the development of disease.	48 (94.1%) 850 (92.6%)	0 (0%) 2 (0.2%)	3 (5.9%) 66 (7.2%)	1.000
6. In this research project one of the major goals is to explore the genetic basis for reactions to prescription drugs.	33 (63.5%) 487 (53.0%)	4 (7.7%) 61 (6.6%)	15 (28.8%) 371 (40.4%)	0.227
7. In the research project, one of the major goals is to establish a DNA database for researchers to use.	41 (80.4%) 679 (74.3%)	0 (0%) 21 (2.3%)	10 (19.6%) 214 (23.4%)	0.648
8. In the research project, one of the researchers' major purposes is to look for genes associated with higher and lower rates of disease.	43 (82.7%) 775 (84.7%)	0 (0%) 6 (0.7%)	9 (17.3%) 134 (14.6%)	0.679
9. The genetic testing in this study will result in my learning which conditions/ diseases I will develop.	16 (30.8%) 254 (27.7%)	19 (36.5%) 358 (39.0%)	17 (32.7%) 306 (33.3%)	0.875
10. My DNA will not be stored as part of this research study.	19 (36.5%) 277 (30.2%)	13 (25.0%) 165 (18.0%)	20 (38.5%) 476 (51.9%)	0.141
11. As part of this study, researchers will have access to my medical records.	40 (80.0%) 490 (53.7%)	4 (8.0%) 187 (20.5%)	6 (12.0%) 236 (25.8%)	0.001
12. After I choose to participate in this research study, my sample will be labeled with my name in order to identify it.	14 (26.9%) 219 (23.9%)	30 (57.7%) 505 (55.1%)	8 (15.4%) 192 (21.0%)	0.604
13. This research project does not carry any risks or discomforts.	39 (75.0%) 675 (73.5%)	2 (3.8%) 125 (13.6%)	11 (21.2%) 118 (12.9%)	0.036
14. There may not be direct medical benefit to me from my participation in this research study.	49 (94.2%) 762 (83.5%)	0 (0%) 37 (4.1%)	3 (5.8%) 114 (12.5%)	0.133
15. By participating in this research study, I am helping the researchers learn information that may benefit future patients.	51 (100%) 902 (98.4%)	0 (0%) 1 (0.1%)	0 (0%) 14 (1.5%)	1.000
16. Because I am participating in a genetics research study, it is possible that the study sponsor, various government agencies, or others who are not directly involved in my care could view my medical records.	20 (39.2%) 221 (24.0%)	20 (39.2%) 421 (45.8%)	11 (21.6%) 278 (30.2%)	0.057
17. The researchers did not offer me any alternative besides involvement in this research study.	18 (36.0%) 271 (29.6%)	24 (48.0%) 454 (49.7%)	8 (16.0%) 189 (20.7%)	0.575
18. The consent form that I signed describes who will pay for my treatment if I am injured or become ill as a result of participation in this research study.	21 (40.4%) 297 (32.6%)	11 (21.2%) 150 (16.5%)	20 (38.5%) 464 (50.9%)	0.195
19. The consent form I signed lists the name of person (or persons) whom I should contact if I have any questions or concerns about this research study.	40 (78.4%) 605 (66.0%)	5 (9.8%) 29 (3.2%)	6 (11.8%) 283 (30.9%)	0.001
20. If I had not wanted to participate in this study, I could have declined to sign the consent form.	51 (98.1%) 893 (97.1%)	1 (1.9%) 4 (0.4%)	0 (0%) 23 (2.5%)	0.184
21. I will have to remain in this research study even if I decide someday that I want to withdraw.	2 (4.2%) 108 (11.7%)	39 (81.3%) 573 (62.3%)	7 (14.6%) 239 (26.0%)	0.027
22. I felt pressured by study personnel to participate in the Personalized Medicine Research Project.	1 (2.1%) 18 (2.0%)	46 (95.8%) 875 (95.9%)	1 (2.1%) 19 (2.1%)	1.000
23. I felt pressured by someone other than the study personnel to participate in the Personalized Medicine Research Project.	0 (0%) 19 (2.1%)	49 (94.2%) 873 (95.8%)	3 (5.8%) 19 (2.1%)	0.149

Statement	Agree	Disagree	Unsure	p-value
24. The $20 greatly influenced my decision to participate in the Personalized Medicine Research Project.	2 (3.8%) 311 (34.3%)	47 (90.4%) 545 (60.0%)	3 (5.8%) 52 (5.7%)	<0.001

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Table 3.

Comparison between current (line 1 in each row) and previous (line 2 in each row) cohorts about statements related to understanding of the PMRP. Higher numbers indicate better understanding.

Statement	N	1	2	3	4	5	p-value
1. The fact that the Personalized Medicine Research Project involves genetic research.	49 913	2.0% 0.7%	2.0% 1.3%	12.2% 7.9%	34.7% 20.2%	49.0% 69.8%	0.002
2. What the researchers are trying to find out in the Personalized Medicine Research Project.	49 913	2.0% 1.1%	2.0% 3.5%	14.3% 21.1%	46.9% 36.9%	34.7% 37.1%	0.750
3. How long you will be in the research study.	46 909	8.7% 4.2%	4.3% 9.5%	23.9% 32.9%	17.4% 24.3%	45.7% 29.2%	0.097
4. The procedures that you will undergo as part of the study.	49 909	0.0% 3.3%	6.1% 5.1%	10.2% 22.2%	36.7% 26.6%	46.9% 42.7%	0.177
5. Which of the procedures are experimental.	46 897	0.0% 9.6%	17.4% 11.5%	23.9% 35.6%	30.4% 22.5%	28.3% 20.8%	0.060
6. The possible risks and discomforts of participating in the Personalized Medicine Research Project.	49 909	0.0% 3.9%	6.1% 4.0%	12.2% 17.9%	36.7% 26.3%	44.9% 48.0%	0.834
7. The possible benefits to you of participating in the Personalized Medicine Research Project.	49 909	4.1% 2.8%	6.1% 3.2%	14.3% 16.1%	30.6% 31.2%	44.9% 46.8%	0.655
8. How your participation in the Personalized Medicine Research Project may benefit future patients.	49 913	0.0% 0.7%	0.0% 1.1%	6.1% 5.9%	20.4% 26.2%	73.5% 66.2%	0.293
9. The alternatives to participation in the Personalized Medicine Research Project.	49 902	6.1% 7.4%	4.1% 7.4%	20.4% 25.6%	20.4% 20.3%	49.0% 39.2%	0.137
10. How the confidentiality of my medical records will be protected under the Personalized Medicine Research Project.	49 909	4.1% 2.4%	0.0% 2.2%	8.2% 12.5%	18.4% 28.2%	69.4% 54.7%	0.062
11. Who will pay for treatment if you are injured or become ill as part of this research study.	49 902	8.2% 8.3%	12.2% 11.6%	20.4% 31.5%	28.6% 18.4%	30.6% 30.0%	0.507
12. Whom you should contact if you have questions or concerns about the Personalized Medicine Research Project.	49 910	2.0% 4.3%	8.2% 6.6%	8.2% 21.0%	28.6% 23.5%	53.1% 44.6%	0.126
13. The fact that participation in the Personalized Medicine Research Project is voluntary.	49 914	0.0% 0.8%	0.0% 0.3%	2.0% 2.6%	8.2% 10.3%	89.8% 86.0%	0.440
14. Overall, how well did you understand the Personalized Medicine Research Project when you signed the consent form.	49 907	0.0% 0.8%	0.0% 2.0%	8.2% 16.3%	51.0% 42.7%	40.8% 38.1%	0.246

Table 4.

Comparison between computer-based consenting (line 1 in each row) and traditional (line 2 in each row) groups about factual statements related to informed consent. Expected responses are highlighted in bold.

Statement	Agree	Disagree	Unsure	p-value
1. When I signed the consent form to have my blood drawn, I knew that I was agreeing to participate in a research project.	25 (100%) 27 (100%)	0 (0%) 0 (0%)	0 (0%) 0 (0%)	1.000
2. The main goal of genetic research studies, such as the Personalized Medicine Research Project, is to improve scientific knowledge for future patients.	25 (100%) 27 (100%)	0 (0%) 0 (0%)	0 (0%) 0 (0%)	1.000
3. I have been informed how long my participation in the Personalized Medicine Research Project is likely to last.	17 (68.0%) 17 (68.0%)	0 (0%) 0 (0%)	8 (32.0%) 8 (32.0%)	1.000
4. All the procedures in the research project are standard for any routine genetic testing.	22 (88.0%) 22 (81.5%)	0 (0%) 0 (0%)	3 (12.0%) 5 (18.5%)	0.705
5. In this research project, one of the major goals is to understand how genes contribute to the development of disease.	24 (96.0%) 24 (92.3%)	0 (0%) 0 (0%)	1 (4.0%) 2 (7.7%)	1.000
6. In this research project one of the major goals is to explore the genetic basis for reactions to prescription drugs.	15 (60.0%) 18 (66.7%)	3 (12.0%) 1 (3.7%)	7 (28.0%) 8 (29.6%)	0.623
7. In the research project, one of the major goals is to establish a DNA database for researchers to use.	20 (80.0%) 21 (80.8%)	0 (0%) 0 (0%)	5 (20.0%) 5 (19.2%)	1.000
8. In the research project, one of the researchers' major purposes is to look for genes associated with higher and lower rates of disease.	21 (84.0%) 22 (81.5%)	0 (0%) 0 (0%)	4 (16.0%) 5 (18.5%)	1.000
9. The genetic testing in this study will result in my learning which conditions/ diseases I will develop.	9 (36.0%) 7 (25.9%)	12 (48.0%) 7 (25.9%)	4 (16.0%) 13 (48.1%)	0.045
10. My DNA will not be stored as part of this research study.	11 (44.0%) 8 (29.6%)	8 (32.0%) 5 (18.5%)	6 (24.0%) 14 (15.9%)	0.137
11. As part of this study, researchers will have access to my medical records.	18 (72.0%) 22 (88.0%)	3 (12.0%) 1 (4.0%)	4 (16.0%) 13 (48.1%)	0.385
12. After I choose to participate in this research study, my sample will be labeled with my name in order to identify it.	5 (20.0%) 9 (33.3%)	16 (64.0%) 14 (51.9%)	4 (16.0%) 4 (14.8%)	0.542
13. This research project does not carry any risks or discomforts.	20 (80.0%) 19 (70.4%)	0 (0%) 2 (7.4%)	5 (20.0%) 6 (22.2%)	0.580
14. There may not be direct medical benefit to me from my participation in this research study.	25 (100%) 24 (88.9%)	0 (0%) 0 (0%)	0 (0%) 3 (11.1%)	0.236
15. By participating in this research study, I am helping the researchers learn information that may benefit future patients.	25 (100%) 26 (100.0%)	0 (0%) 0 (0%)	0 (0%) 0 (0%)	1.000
16. Because I am participating in a genetics research study, it is possible that the study sponsor, various government agencies, or others who are not directly involved in my care could view my medical records.	10 (40.0%) 10 (38.5%)	9 (36.0%) 11 (42.3%)	6 (24.0%) 14 (15.9%)	0.936
17. The researchers did not offer me any alternative besides involvement in this research study.	4 (16.0%) 14 (56.0%)	16 (64.0%) 8 (32.0%)	5 (20.0%) 3 (12.0%)	0.013
18. The consent form that I signed describes who will pay for my treatment if I am injured or become ill as a result of participation in this research study.	14 (56.0%) 7 (25.9%)	5 (20.0%) 6 (22.2%)	6 (24.0%) 14 (41.9%)	0.065
19. The consent form I signed lists the name of person (or persons) whom I should contact if I have any questions or concerns about this research study.	20 (83.3%) 20 (74.1%)	2 (8.3%) 3 (11.1%)	2 (8.3%) 4 (14.8%)	0.787
20. If I had not wanted to participate in this study, I could have declined to sign the consent form.	24 (96.0%) 27 (100.0%)	1 (4.0%) 0 (0%)	0 (0%) 0 (0%)	0.481
21. I will have to remain in this research study even if I decide someday that I want to withdraw.	1 (4.2%) 1 (4.2%)	21 (87.5%) 18 (75.0%)	2 (8.3%) 5 (20.8%)	0.701
22. I felt pressured by study personnel to participate in the Personalized Medicine Research Project.	0 (0%) 1 (4.2%)	24 (100%) 22 (91.7%)	0 (0%) 1 (4.2%)	0.489
23. I felt pressured by someone other than the study personnel to participate in the Personalized Medicine Research Project.	0 (0%) 0 (0%)	23 (92.0%) 26 (96.3%)	2 (8.0%) 1 (3.7%)	0.603

Statement	Agree	Disagree	Unsure	p-value
24. The $20 greatly influenced my decision to participate in the Personalized Medicine Research Project.	1 (4.0%) 1 (3.7%)	24 (96.0%) 23 (85.2%	0 (0%) 3 (11.1%)	0.236

Table 5.

Comparison between computer-based consenting (line 1 in each row) and traditional (line 2 in each row) groups related to understanding of the PMRP. Higher numbers indicate better understanding.

Statement	N	1	2	3	4	5	p-value
1. The fact that the Personalized Medicine Research Project involves genetic research.	22 27	0.0% 3.7%	0.0% 3.7%	4.5% 18.5%	45.5% 25.9%	50.0% 48.1%	0.411
2. What the researchers are trying to find out in the Personalized Medicine Research Project.	22 27	0.0% 3.7%	0.0% 3.7%	9.1% 18.5%	45.5% 48.1%	45.5% 25.9%	0.076
3. How long you will be in the research study.	21 25	0.0% 16.0%	0.0% 8.0%	28.6% 20.0%	14.3% 20.0%	57.1% 36.0%	0.081
4. The procedures that you will undergo as part of the study.	22 27	0.0% 0.0%	4.5% 7.4%	0.0% 18.5%	40.9% 33.3%	54.5% 40.7%	0.155
5. Which of the procedures are experimental.	22 24	0.0% 0.0%	4.5% 29.2%	27.3% 20.8%	40.9% 20.8%	27.3% 29.2%	0.259
6. The possible risks and discomforts of participating in the Personalized Medicine Research Project.	22 27	0.0% 0.0%	0.0% 11.1%	9.1% 14.8%	40.9% 33.3%	50.0% 40.7%	0.255
7. The possible benefits to you of participating in the Personalized Medicine Research Project.	22 27	0.0% 7.4%	0.0% 11.1%	13.6% 14.8%	36.4% 25.9%	50.0% 40.7%	0.198
8. How your participation in the Personalized Medicine Research Project may benefit future patients.	22 27	0.0% 0.0%	0.0% 0.0%	4.5% 7.4%	18.2% 22.2%	77.3% 70.4%	0.584
9. The alternatives to participation in the Personalized Medicine Research Project.	22 27	0.0% 11.1%	4.5% 3.7%	13.6% 25.9%	18.2% 22.2%	63.6% 37.0%	0.046
10. How the confidentiality of my medical records will be protected under the Personalized Medicine Research Project.	22 27	0.0% 7.4%	0.0% 0.0%	4.5% 11.1%	18.2% 18.5%	77.3% 63.0%	0.211
11. Who will pay for treatment if you are injured or become ill as part of this research study.	22 27	0.0% 14.8%	9.1% 14.8%	22.7% 18.5%	27.3% 29.6%	40.9% 22.2%	0.078
12. Whom you should contact if you have questions or concerns about the Personalized Medicine Research Project.	22 27	0.0% 3.7%	4.5% 11.1%	9.1% 7.4%	27.3% 29.6%	59.1% 48.1%	0.359
13. The fact that participation in the Personalized Medicine Research Project is voluntary.	22 27	0.0% 0.0%	0.0% 0.0%	0.0% 3.7%	9.1% 7.4%	90.9% 88.9%	0.803
14. Overall, how well did you understand the Personalized Medicine Research Project when you signed the consent form.	22 27	0.0% 0.0%	0.0% 0.0%	0.0% 14.8%	54.5% 48.1%	45.5% 37.0%	0.275