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Comprehension and Informed Consent: Assessing the Effect of a Short Consent Form

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Although informed consent is a fundamental ethical requirement for research with humans, many studies indicate that research volunteers often do not understand critical aspects of the research in which they are participating, suggesting that the "informed" part of consent to participate is imperfectly realized.[1] For instance, a study of 287 adult cancer patients participating in clinical trials revealed that 70% of patient-subjects did not recognize the unproven nature of the study drug.[2] At the same time, concerns have arisen that the increasing length and complexity of consent forms are inhibiting information disclosure and impeding understanding.[3] Consequently, critics worry that the informed consent process does not accomplish the goal of adequately informing prospective participants about the nature of a study and its potential risks and benefits.

Several attempts at improving informed consent have been evaluated.[4] Some preliminary and small studies suggest that decreasing the length and complexity of consent forms may improve understanding, satisfaction with the informed consent process, or both.[5] However, not all studies found improvement.[6] Moreover, these studies have important limitations. Many used consent documents in hypothetical situations rather than in actual research

Disclaimer: Ms. Stunkel had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

studies.[7] Also, most of the consent studies involved participants who were receiving a study intervention for a disease or disorder[8] and thus may not apply to healthy volunteers who participate in phase I drug development research.

Another concern about the quality of informed consent is the fear that prospective research participants, preoccupied by the prospect of financial gain, will ignore details of the research provided during the consent process, yielding poor understanding of risks, benefits, and alternatives. Yet there are few data about the impact of financial motivations on volunteers' understanding of the studies in which they agree to participate.

To address some of these concerns, our study evaluated the effect of a shorter and simpler consent form on the comprehension and satisfaction of research participants. We hypothesized that study volunteers would have the same level of comprehension after reading either a standard or a concise consent form, and that they would be more satisfied with the concise consent form. We also hypothesized that comprehension might be affected by select volunteer characteristics, including financial motivations to participate in research.

Study Methods

This was a substudy of a phase I bioequivalence study involving healthy volunteers conducted by Pfizer at its Clinical Research Unit in New Haven, Connecticut. The study compared a new 80-milligram atorvastatin calcium chewable tablet to an 80-milligram commercial atorvastatin calcium tablet formulation. From October 2008 to January 2009, all of the healthy individuals who came to the Clinical Research Unit to consider enrolling in the atorvastatin study were invited to participate in the informed consent substudy; only adults (age 18 and over) who could give their own informed consent were included in either the atorvastatin study or the informed consent substudy.

Participants were randomized by date of their visit to the Clinical Research Unit to receive either the standard consent form or the concise consent form. Both contained the elements required by the federal regulations governing research with humans, which are intended to provide all the information necessary to make an informed, voluntary decision to participate.[9] Investigators from Pfizer wrote the standard consent form, and investigators from the Department of Bioethics at the National Institutes of Health Clinical Center wrote the experimental concise consent form. The consent forms differed substantially by their number of words, length and complexity of sentences, and readability level (Table 1). The difference in length between the two forms was accomplished by eliminating repetition and unnecessary detail and using more simplified language (Table 2). Immediately after reading the consent form, participants in the substudy completed a self-administered survey instrument; they could not refer back to the consent form while filling out the questionnaire. After completing the questionnaire, those interested in participating in the atorvastatin study completed the standard Pfizer consent process. This consisted of a detailed verbal explanation of each paragraph of the consent form, followed by a question and answer session given by qualified research personnel. All volunteers in the atorvastatin study ultimately signed the standard consent form.

Survey development consisted of: 1) a comprehensive literature review; 2) draft survey development followed by iterative review and revision by investigators; 3) cognitive, behavioral, and reliability pretesting with healthy volunteers at the NIH; and 4) final revisions. The survey instrument contained 36 items assessing comprehension, satisfaction, motivation, and sociodemographic characteristics. The comprehension section consisted of 15 multiple-choice questions focusing on the basic elements of informed consent required by federal regulations and the rules and procedures of the Clinical Research Unit. Questions assessed whether respondents understood 1) that they would be participating in a research study and that participation was voluntary; 2) the study's purpose and research procedures; 3) the potential risks and benefits of the study; and 4) the confidentiality protections that were in place. A comprehension score was calculated by awarding one point for correct answers and zero points for incorrect answers, “I do not know” responses, and questions left blank (possible score 0–15). Simple descriptive statistics and frequency distributions described the variables. Two-sample t-tests were used to compare continuous variables unless data were not normally distributed, in which case results from the Wilcoxon rank sum test were reported. Univariate regression analyses were used to assess correlations between two continuous variables. Fisher's exact tests compared categorical data. If categories of data were ordered, tests for trend were performed using nonparametric rank tests. Analysis of variance (ANOVA) was used to compare continuous variables in 2+ categories, and the Abelson-Tukey ANOVA test for trend was used for assessing trend in these categories. Using a two-sided alpha of 0.05, a prospective noninferiority power calculation yielded 87.1% power for our study. A p-value ≤ 0.05 was considered statistically significant. Data are presented as mean ± standard deviation (SD), unless otherwise specified. All data were analyzed using SAS v9.1 (SAS Institute Inc., Cary, North Carolina).

Study Results

A total of 139 individuals were approached to participate in the informed consent substudy and all agreed; 138 returned a completed questionnaire (response rate = 99.3%). The two cohorts were virtually identical in sociodemographic characteristics. Nearly three-quarters were male (73%), and the mean age of the volunteers was 36 years. About half of the study volunteers were African American and one-third were Caucasian; one-fourth of the volunteers identified themselves as Hispanic. Most volunteers (74%) had attended at least some college, and 43% were unemployed. The majority (54%) lacked health insurance. Fully 80% had participated in at least one previous research study, with over one-third having participated in four or more previous studies.

Comprehension

Volunteers in both cohorts scored well overall on the comprehension section. Out of 15, the standard consent cohort had an average score of 11.1 (±2.8), and the concise consent cohort had an average score of 11.5 (±2.5, p = 0.55). However, certain questions were difficult for both cohorts (Table 3). The only significant difference between the two cohorts related to what volunteers were expected to do off-site between study periods. The concise consent cohort answered this question correctly more often than the standard consent cohort (97% vs. 87%; p = 0.03) (Table 3).

Gender, age, employment, and previous research participation were not associated with greater comprehension. However, there was a slight association between higher education level and greater comprehension; volunteers without a college education scored lower than those with at least some college education (10.7 ± 2.6 vs. 11.6 ± 2.5, p = 0.035).

Satisfaction

Satisfaction with the consent form was similar between cohorts. In both cohorts, almost all volunteers rated the length and amount of detail of their respective consent form as “about right.” The few volunteers who thought otherwise reported too much detail for the standard consent form (6%) or not enough detail for the concise consent form (4.5%, p = 0.03 for trend) (Table 4). All volunteers (100%) were satisfied with the organization of their respective consent form. Over 90% of volunteers were at least somewhat satisfied with what they learned about the study and found the information in the consent form very or moderately helpful to their decision. Almost all (97%) reported feeling moderately or well informed about the study, and most reported getting all of the information they wanted. There was no correlation between comprehension and how well informed volunteers felt, how carefully they read the consent form, whether they had difficulty understanding the consent form, or whether they were satisfied with what they had learned about the study.

Voluntariness

Every volunteer knew that he or she could refuse to join the study, and 84% knew that they could stop participating at any time. Only three volunteers reported feeling any pressure to join the study—two of them from a friend, and one from the research staff. There were no differences noted in these features between the standard consent and concise consent cohorts.

Motivations for Study Participation

The majority of volunteers (58%) reported that their primary motivation for participating in the study was financial, while 29% reported nonfinancial motivations, and 13% reported a mix of both. Those volunteers who reported a primary financial motivation had significantly greater comprehension compared to volunteers with a primary nonfinancial motivation (12.0 ± 2.3 vs. 10.3 ± 2.9; p = 0.0005).

Discussion

This randomized controlled study of standard versus concise consent forms used in a phase I drug development trial revealed relatively high overall comprehension among healthy volunteers. The longer consent form did not generate greater comprehension, and the concise form did not enhance satisfaction. Surprisingly, volunteers who reported financial considerations to be their primary motivation for participating had significantly greater comprehension.

The standard and concise cohorts had similar comprehension. The cohorts did not differ in overall comprehension score or proportions of correct responses to individual questions. Volunteers had the same level of comprehension after reading a 14-page or a four-page

consent form. This suggests that too much attention is spent on the details of consent forms, possibly as a result of legal liability issues. Time spent revising the small details and specific wording of informed consent documents does not appear to impact comprehension. Shorter, more readable consent forms appear to have no adverse effect on the quality of informed consent. In the future, it would be acceptable for institutional review boards (IRBs) to approve shorter forms for use in human subjects research. Moreover, it would be appropriate for IRBs to allow future randomized studies of shorter informed consent forms, like this one, to be approved as minimal-risk studies.[10]

Certain questions were more difficult than others for both groups, particularly those asking about the possibility of personal benefit, who had access to their records, and whether respondents knew this was the first test in humans of the chewable form of atorvastatin. Both groups scored better on questions related to study purpose, procedures, possible risks, and especially payment and rules of the Clinical Research Unit. This could indicate that volunteers in phase I studies are more interested in certain aspects of study information. It would be useful to do further research on what information healthy volunteers use to make decisions about research participation.

The two cohorts reported no significant difference in any measure of satisfaction we assessed. Interestingly, about 95% of volunteers in both cohorts reported that they found the length of the consent form to be “About right,” despite the 10-page difference between the two documents. This surprising result suggests that the length of the form had a much lower effect on satisfaction than expected. Respondents in our study did not appear to feel overwhelmed by a long consent form or uninformed by a short one. Thus, a shift to shorter forms could be financially preferable in order to save on time both in writing a consent form and reviewing it with potential research participants. Although it is possible that some respondents in our study may have chosen certain answers because of concerns that if they criticized Pfizer in their responses to the survey questions, they would jeopardize their eligibility to participate in the main study, we attempted to allay these concerns by informing them that the Pfizer investigators would not see their individual answers.

Our findings challenge the concern that people who enroll in research for financial reasons are likely to be blinded by money and may not read the consent form, or may ignore details and fail to understand what they are doing with regard to research participation.[11] Furthermore, there was no correlation between previous research participation and greater comprehension, so previous research experience is not a confounding factor in this result. Accordingly, our findings support the idea that money does not adversely affect individuals' understanding of the risks and details of the study in which they were recruited to participate.[12] One possible explanation for this unexpected result is that people motivated by financial remuneration conceive of research participation as a business transaction and strive to be informed consumers.[13] Indeed, they may pay attention to the details of the study because, being motivated by payment, they can seek out a study that fits their preferences. On the other hand, the details of a particular study may have less influence on the decisions of a person who is motivated to enroll in a clinical trial because of their interest in research on a particular disease or because they will receive a specific intervention. There is a need

for further research to better understand the association between motivations and comprehension of study information.

Notably, our findings negate the common claim that socioeconomically disadvantaged research participants have poor comprehension of study information and thus require special protections.[14] Nearly two-thirds of the volunteers in the main phase I study were from minority groups, 43% were unemployed, and over half were uninsured. Nevertheless, overall comprehension scores were good, and none of the sociodemographic variables we measured affected comprehension. Only lower education level was associated with lower comprehension, supporting what has been shown in other studies.[15] Perhaps this is because one of the explicit goals of education is to increase reading comprehension skills.

This study has several limitations. First, the main study was a low-risk, phase I bioequivalence study of a marketed drug which took place at a single clinical research facility, and the findings may not generalize to first-in-human studies, phase I oncology studies, phase II and phase III studies, or other phase I research facilities. Additionally, there is no “gold standard” instrument for comprehension, in part because comprehension tests must be tailored to the details of the particular study. In an attempt to account for this problem, the comprehension questions used in this study focused on the elements of consent required by federal regulations governing research with humans. However, a possible bias in results could have occurred because the investigators who wrote the comprehensive questions also wrote the concise consent form.

We found that neither comprehension of study information nor satisfaction with the consent process was affected by either the length or the complexity of the consent form. Surprisingly, the results show that respondents who said that they were motivated to enroll in the main study because they would be paid to participate had higher comprehension. Although there may be compelling reasons to write simpler consent forms, more data are needed to determine whether simpler consent forms are better than longer, more complex ones. Nonetheless, researchers should aim to distill the information necessary for informed consent in a comprehensible manner, and consent templates to assist investigators in writing concise consent forms may be useful. Finally, additional research is needed to elucidate the relationships among motivations, payment, and comprehension.

Acknowledgments

The atorvastatin study was approved by IntegReview, an independent, commercial IRB, according to usual procedures at the Pfizer Clinical Research Unit. The informed consent substudy was approved by the Combined Neurosciences IRB at the National Institutes of Health. Individuals were invited verbally to participate in the substudy. The questionnaire stated the substudy purpose, that confidentiality was protected, and that participation was voluntary and would not affect eligibility for the atorvastatin or other Pfizer studies.

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References

1. Fortun P, West J, Chalkley L, et al. Recall of informed consent information by healthy volunteers in clinical trials. Quarterly Journal of Medicine. 2008; 101:625–629.Lynoe N, Sandlund M, Dahlqvist

G, et al. Informed consent: Study of quality of information given to participants in a clinical trial. BMJ. 1991; 303:610–613. [PubMed: 1932901]

2. Joffe S, Cook EF, Cleary PD, et al. Quality of informed consent in cancer clinical trials: A cross-sectional survey. Lancet. 2001; 358:1772–1777. [PubMed: 11734235]
3. Grossman SA, Piantadosi S, Covahey C. Are informed consent forms that describe clinical oncology research protocols readable by most patients and their families? Journal of Clinical Oncology. 1994; 12:2211–2215. [PubMed: 7931491] Mader TJ, Playe SJ. Emergency medicine research consent form readability assessment. Annals of Emergency Medicine. 1997; 29:534–539. [PubMed: 9095017] Paasche-Orlow MK, Taylor HA, Brancati FL. Readability standards for informed-consent forms as compared with actual readability. NEJM. 2003; 348:721–726. [PubMed: 12594317]
4. Flory J, Emanuel E. Interventions to improve research participants' understanding in informed consent for research: A systematic review. JAMA. 2004; 292:1593–1601. [PubMed: 15467062]
5. Epstein LC, Lasagna L. Obtaining informed consent. Form or substance. Archives of Internal Medicine. 1969; 123:682–688. [PubMed: 5771055] Young DR, Hooker DT, Freeberg FE. Informed consent documents: Increasing comprehension by reducing reading level. IRB: Ethics & Human Research. 1990; 12:1–5. [PubMed: 11651387] Rogers CG, Tyson JE, Kennedy KA, et al. Conventional consent with opting in versus simplified consent with opting out: An exploratory trial for studies that do not increase patient risk. Journal of Pediatrics. 1998; 132:606–611. [PubMed: 9580757] Bjorn E, Rossel P, Holm S. Can the written information to research subjects be improved? —an empirical study. Journal of Medical Ethics. 1999; 25:263–267. [PubMed: 10390684] Murphy DA, O'Keefe ZH, Kaufman AH. Improving comprehension and recall of information for an HIV vaccine trial among women at risk for HIV: Reading level simplification and inclusion of pictures to illustrate key concepts. AIDS Education and Prevention. 1999; 11:389–399. [PubMed: 10555623] Dresden GM, Levitt MA. Modifying a standard industry clinical trial consent form improves patient information retention as part of the informed consent process. Academic Emergency Medicine. 2001; 8:246–252. [PubMed: 11229946]
6. Taub HA, Baker MT, Sturr JF. Informed consent for research. Effects of readability, patient age, and education. Journal of the American Geriatrics Society. 1986; 34:601–606. [PubMed: 3722678] Davis TC, Holcombe RF, Berkel HJ, et al. Informed consent for clinical trials: A comparative study of standard versus simplified forms. Journal of the National Cancer Institute. 1998; 90:668–674. [PubMed: 9586663] Stiles PG, Poythress NG, Hall A, et al. Improving understanding of research consent disclosures among persons with mental illness. Psychiatric Services. 2001; 52:780–785. [PubMed: 11376225] ; see ref. 5, Bjorn et al. 1999; Coyne CA, Xu R, Raich P, et al. Randomized, controlled trial of an easy-to-read informed consent statement for clinical trial participation: A study of the Eastern Cooperative Oncology Group. Journal of Clinical Oncology. 2003; 21:836–842. [PubMed: 12610182]
7. See ref. 5, Epstein and Lasagna 1969; see ref. 5, Young et al. 1990; see ref. 5, Bjorn et al. 1999; see ref. 5, Murphy et al. 1999; see ref. 5, Dresden and Levitt 2001.
8. See ref. 5, Dresden and Levitt 2001; see ref. 5, Rogers et al. 1998; see ref. 6, Taub et al. 1986; see ref. 6, Coyne et al. 2003.
9. 45 CFR 46.116 and 21 CFR 50.25.
10. See ref. 5, Rogers et al. 1998; Menikoff J. Case study Is longer always better? Commentary. Hastings Center Report. 2008; 38:11–12. [PubMed: 18581930] Sachs GA, Hougham GW, Sugarman J, et al. Conducting empirical research on informed consent: Challenges and questions. IRB: Ethics & Human Research. 2003; Suppl 25:S4–S10. [PubMed: 14870730]

11. Denny CC, Grady C. Clinical research with economically disadvantaged populations. Journal of Medical Ethics. 2007; 33:382–385. [PubMed: 17601862] Macklin R. On paying money to research subjects: “Due” and “undue” inducements. IRB: Ethics & Human Research. 1981; 3:1–6. [PubMed: 11649367] Lemmens T, Elliott C. Guinea pigs on the payroll: The ethics of paying research subjects. Accountability in Research. 1999; 7:3–20. [PubMed: 11657561]

12. Grady C. Money for research participation: Does it jeopardize informed consent? American Journal of Bioethics. 2001; 1:40–44. [PubMed: 11951886] Grady C. Payment of clinical research subjects. Journal of Clinical Investigation. 2005; 115:1681–1687. [PubMed: 16007244] McNeill P. Paying people to participate in research: Why not? A response to Wilkinson and Moore. Bioethics. 1997; 11:390–396. [PubMed: 11655118]

13. Lemmens T, Elliott C. Justice for the professional guinea pig. American Journal of Bioethics. 2001; 1:51–53. [PubMed: 11951892] Anderson JA, Weijer C. The research subject as entrepreneur. American Journal of Bioethics. 2001; 1:67–69. [PubMed: 11951902]

14. See ref. 2, Joffe et al. 2001; see ref. 11, Denny and Grady 2007; Howard JM, DeMets D. How informed is informed consent? The BHAT experience. Controlled Clinical Trials. 1981; 2:287–303. [PubMed: 6120794]

15. See ref. 2, Joffe et al. 2001; see ref. 5, Young et al. 1990; see ref. 6, Taub et al. 1986; see ref. 14, Howard and DeMets 1981; Beardsley E, Jefford M, Mileshkin L. Longer consent forms for clinical trials compromise patient understanding: So why are they lengthening? Journal of Clinical Oncology. 2007; 25:e13–14. [PubMed: 17369564]

Table 1
Comparing the Standard and Concise Consent Forms

	Standard	Concise
Total Pages *	14	4
Total Word Count *	5,716	2,153
Words in Heading, Introduction, and Purpose Section	392	140
Words in Benefits Section	39	29
Words in Risk Section	340	210
Words in Alternatives Section	25	52
Words in Procedures Section	2,167	1,039
Words in Birth Control Procedures Section	583	200
Words in Payment Section	575	154
Words in Payment for Injury Section	181	86
Words in Confidentiality Section	327	119
Words Relating to Legal and Informed Consent Issues	938	65
Words in Contact Section	185	60
Flesch-Kincaid Reading Level * (Grade Level)	8.9	8.0

* Page number, word count, and Flesch-Kincaid Reading Level were measured using the readability statistics feature of Microsoft® Office Word 2003.

Table 2

Sample of the Wording Differences Between the Standard and Concise Consent Forms (Birth Control Procedures Section)

STANDARD

DANGERS OF PREGNANCY AND BIRTH CONTROL

It is very important that women do not become pregnant and men do not make women pregnant during this study. The only certain way to prevent pregnancy is to not have sex. If you are a woman and choose to have sex during this study, you must use a medically proven, acceptable type of birth control. If you are a man and choose to have sex with a fertile woman, you and your partner must use a medically proven type of birth control throughout the study.

If you become pregnant during the study, you will be discontinued from study participation for safety reasons. If you become pregnant within 28 days after you have stopped taking the study drug, we ask that you contact the study doctor for safety monitoring. In either case, please make your obstetrician aware of your study participation. The study doctor will ask that you, or your obstetrician, provide updates on the progress of your pregnancy and its outcome. The study doctor will make this information available to the study sponsor for safety monitoring follow-up.

A pregnancy test could be wrong and if you become pregnant during the study, you may be receiving the study drug while pregnant. The effects of the study drug on an unborn or breastfed baby are unknown. If you become pregnant during the study, call the study doctor at once.

It is very important that men do not make women pregnant during this study. The only certain way to prevent pregnancy is to not have sex. If you are a man and choose to have sex with a fertile woman, you and your partner must use a medically proven type of birth control from the first day of dosing until 28 days after the last dose of the study drug.

If your partner becomes pregnant during the study until 28 days after last dose or is already pregnant at the time of the study start, you should inform us immediately. She will be asked to sign a consent form to allow the study doctor or her obstetrician to collect updates on the progress of the pregnancy and its outcome. The study doctor will make this information available to the study sponsor for safety monitoring follow-up.

Acceptable methods of birth control for this study include:

For MALES

- Abstinence

OR

- Use of a condom for males who have had a vasectomy more than six months from the first day of dosing

OR

- Condom PLUS female partner with one of the following methods:
  - Tubal ligation (tubes tied)
  - Hysterectomy
  - Both ovaries removed
  - Copper containing intrauterine device (IUD)
  - Diaphragm with spermicide
  - Spermicidal foam/gel/film/cream/suppository
  - Birth control pills
  - Injectable progesterone
  - Subdermal (under the skin) contraceptive implant

These methods should be used before the first dose of the study drug through 28 days of the last dose.

FOR FEMALES

- Abstinence

OR

TWO of the following methods:

- Tubal ligation (tubes tied)
- Diaphragm
- Males who have had a vasectomy more than six months from the first day of dosing
- Spermicidal foam/gel/film/cream/suppository

These methods should be used from 14 days prior to the first dose until 28 days after last dose of the study drug.

Even if you use a medically proven birth control method, there is a chance a pregnancy could occur.

If you are pregnant or become pregnant during the study, the study drug may involve risks to the unborn baby, which are currently unforeseeable.

CONCISE

What about birth control while you are in this study?

Because we do not know the effects of the study drug on unborn fetuses or on sperm, both men and women must avoid pregnancy during the study. The most certain way to avoid pregnancy is to not have sex. If you choose to have sex, you must use an effective method of birth control from the time of the first dose of the study drug until 28 days after the second dose of the study drug. If you are a woman and can have children,

you **cannot** use hormonal birth control, but **must** use **two** of the following: condoms, diaphragm, spermicidal gels or creams, or tubal ligation. If you are a male and have not had a vasectomy (or have had a vasectomy within the previous six months), you **must** use a condom and have your partner use another form of birth control (such as a diaphragm, birth control pills, foam). If you had a vasectomy more than six months ago, you should still use a condom to prevent passing the drug to your partner. If you or your partner does become pregnant, we will ask for information about the pregnancy.

Table 3

Comprehension Score

Comprehension	Standard N = 68 n (%)*	Concise N = 70 n (%)*	Total N = 138 n (%)*	P-value
Mean ± SD	**11.1±2.8**	**11.5±2.5**	**11.3±2.7**	**0.55**
Median (range)	**11 (3-15)**	**12 (1-15)**	**12 (1-15)**	
Questions	**Number Correct (% Correct)**			
About how many weeks will you be in the chewable atorvastatin study? one, **three**, five, seven, or I do not know	43 (63)	47 (68)	90 (66)	0.59
In this study, you will stay overnight for four nights in the CRU during two study periods.				
What will happen between the two study periods?				
I will take atorvastatin at home				
I will not take any medication at home	58 (87)	67 (97)	125 (92)	0.03
I will be screened for another study				
I do not know				
How do you think your health will benefit from being in this chewable atorvastatin study?				
I am less likely to become obese				
I am likely to see my cholesterol go down				
I am not likely to get health benefits	40 (59)	32 (46)	72 (53)	0.17
I am likely to see my blood pressure go down				
I do not know				
How much do you expect to be paid for your participation in the chewable atorvastatin study?	67 (99)	67 (97)	134 (98)	1.0
About $500, **$2,000**, $5,000, $1,000, or I do not know				
Which of the following best describes atorvastatin? Atorvastatin is …				
An experimental medication that might be useful for obesity				
A medication that is available in pill form for lowering cholesterol	62 (91)	65 (94)	127 (93)	0.53
A medication that is available in pill form for lowering blood pressure				
I do not know				
The chewable form of atorvastatin is:				
An approved drug available on the market for about two years				
An investigational drug that has been tested on about 200 people				
An investigational drug that has not yet been tested in people	36 (55)	37 (56)	73 (55)	1.0
I do not know				
If you join the chewable atorvastatin study, which group will you be in?				
I will be in the group that only gets a chewable pill each time they stay in the CRU				
I will be a in the group that gets to pick which pill they want each time				
I will be in a group that will get both the chewable pill and the pill to swallow at different times during the study	51 (76)	57 (81)	108 (79)	0.53
I do not know				
While confined to the CRU, volunteers are **not** allowed to do which of the following?	61 (91)	66 (96)	127 (93)	0.32

Comprehension	**Standard N = 68 n (%)***	**Concise N = 70 n (%)***	**Total N = 138 n (%)***	**P-value**
Mean ± SD	**11.1±2.8**	**11.5±2.5**	**11.3±2.7**	**0.55**
Median (range)	**11 (3-15)**	**12 (1-15)**	**12 (1-15)**	
Questions	**Number Correct (% Correct)**			
Talk on the phone, Sleep past 10 a.m., **Smoke cigarettes**, or I do not know				
Based on the experience of people who have taken the approved form of atorvastatin, a *possible* risk of it is:	51 (77)	59 (84)	110 (81)	0.38
Diarrhea, Hair loss, Fainting, Bad rash, or I do not know (Choosing multiple responses including the correct answer was considered correct)				
If you decide you do not want to finish the chewable atorvastatin study, or if you are unable or unwilling to do what the study requires, how much will you be paid?				
I will still get the full amount of money for my group				
I will get half of the money I would have received if I had finished				
I will get an amount of money based on what I have already done	63 (94)	66 (94)	129 (94)	1.0
I do not know				
If you choose to have sex during your study participation, you must use certain kinds of birth control. If you are a female, you must use:				
I am male and so do not remember what females must use	43 (65)	46 (67)	89 (66)	0.86
Either a condom, diaphragm, spermicidal gels or creams, or tubal ligation				
Two of these: condom, diaphragm, spermicidal gels or creams, or tubal ligation				
Birth control pills				
I do not know				
How likely it is that you will have side effects from taking atorvastatin?				
Impossible (0% chance)				
There is a one in three chance (33% chance)				
No one really knows	41 (61)	45 (66)	86 (64)	0.59
Certain (100% chance)				
I do not know				
If you join, when are you allowed to stop participating in the chewable atorvastatin study?				
Only when the research staff says I can				
Only after I have taken two doses of atorvastatin				
Anytime I want	60 (90)	56 (80)	116 (85)	0.16
I do not know				
Although Pfizer study staff will protect the confidentiality of your medical information, which one of the following groups may have access to your records without asking you:				
Yale New Haven Medical Center				
Pfizer Inc.	39 (58)	41 (59)	80 (58)	1.0
Connecticut Department of Health				
I do not remember because this is not important to me				
I do not know				
What is the *main* purpose of the chewable atorvastatin study? The main purpose is to find out:				
How long it takes to chew an investigational atorvastatin pill				

Comprehension	**Standard N = 68 n (%)***	**Concise N = 70 n (%)***	**Total N = 138 n (%)***	**P-value**
Mean ± SD	**11.1±2.8**	**11.5±2.5**	**11.3±2.7**	**0.55**
Median (range)	**11 (3-15)**	**12 (1-15)**	**12 (1-15)**	
Questions	**Number Correct (% Correct)**			
If taking higher doses of atorvastatin helps people lower their cholesterol				
Whether the level of atorvastatin in your blood is similar if you take it as a pill to swallow or as a chewable pill	48 (73)	54 (77)	102 (75)	0.56
I do not know (Choosing multiple responses including the correct answer was considered correct)				

*Percents may be based on total number of volunteers providing a response to the particular question and may not equal the total number of volunteers included in the study; missing responses were assigned a score of 0 when computing the total comprehension score.

Table 4
Satisfaction in the Standard Consent Cohort versus the Concise Consent Cohort

Satisfaction	Standard N = 68 n (%)*	Concise N = 70 n (%)*	P-value
Very or somewhat satisfied with what they learned about the study	66 (97)	64 (91)	0.27
Said the length of consent form was:			
Too short	0 (0)	2 (3.0)	0.06
About right	63 (94)	64 (96)	
Too long	4 (6.0)	1 (1.5)	
Said the amount of detail in consent form was:			
Too detailed	4 (6.0)	0 (0)	0.03
About right	62 (93)	64 (96)	
Not detailed enough	1 (1.5)	3 (4.5)	
Said the organization of the consent form was:			
Well organized	17 (25)	27 (40)	0.07
About right	51 (75)	40 (60)	
Not well organized	0 (0)	0 (0)	
Said the information in the consent form was very or moderately helpful to the decision to join the study	66 (97)	62 (93)	0.27
Said they got all the study information they wanted	61 (90)	57 (83)	0.32
Felt very or moderately well informed about the study	66 (97)	68 (97)	1.00
Found the information in the consent form:			
Very or moderately hard	1 (1.5)	3 (4.5)	0.49
Neither hard nor easy	14 (21)	6 (9.0)	
Very or moderately easy	53 (78)	58 (87)	

* Percents may be based on total number of volunteers providing a response to the particular question and may not equal the total number of volunteers included in the study.