

Who Understands? A Survey of 25 Words or Phrases Commonly Used in Proposed Clinical Research Consent Forms

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We all write excellent consent forms to be presented to prospective participants in clinical research studies. That is, we think that they are excellent. But many times consent forms are written from our jaded perspective and contain terms of clinical research jargon, common to us, but foreign to a participant. These terms slip through unnoticed because of their familiarity in our everyday language.

In a recent study¹ a computer analysis (Flesh-Fry scoring)²⁻⁴ of 71 consent forms at a midwest university showed that a mean U.S. school grade for 70 percent comprehension was about 15. In simple terms this means that you would have had to complete your junior year in college to understand 70 percent of the language in the consent forms, which implies about 37 percent of the U.S. adult population could read them. Similar analyses were done with columns of Ann Landers, articles from *Reader's Digest*, and columns from the *New Yorker*. Analysis of Ann Landers columns showed readability by a median seventh grader and by 75 percent of the U.S. adult population. *Reader's Digest* articles yielded data showing a readability by a 10th grader or about 60 percent. Lastly, analysis of the *New Yorker* columns revealed they were readable by only about 43 percent of the U.S. population. In short, these three widely published columns and articles all were more easily read than the analyzed consent forms. It was the authors' opinion that in their case IRB review did little to improve readability. In the above study 64 of the 71 consent forms received final IRB approval. Eighty percent of the forms were revised according to the IRBs' wishes. No forms improved by more than a grade reading level and eight of the forms actually worsened. Prior studies have also shown that most consent forms are not readable by the general population.⁵⁻⁹

In our IRB meetings we often question some of the terms that appear in the text. The clinical research jargon runs rampant in many cases and would appear to confuse the lay reader. In an effort to answer some of these questions we designed a questionnaire to quiz a cross-section of the population on their understanding of many of these terms. In the spring and summer of 1992 the survey was conducted in person by the interviewer on an individual basis. Many of the answers were predictable. Some were surprising!

The questionnaire was on standard 8 1/2 x 11 plain bond with demographic information on top of the first page, such as gender, place of interview, occupation, and maximum educational level. This was followed by the paragraph below:

The questions that follow are to help determine the basic understanding of a patient or subject in a clinical research study after reading a consent form. This will help medical professionals write more understandable research consent forms in the future.

The 25 terms presented in interrogatory sentences followed down the left hand side of the page on the front and back sides. A line for the answer followed each of the 25 sentences.

A total of 287 individuals (126 males and 161 females) were interviewed in California, Florida, New Jersey, Pennsylvania, Rhode Island, and Texas. Subjects were approached randomly in the various settings. Fewer than a half dozen refused to participate. Interviews were conducted in offices, malls, homes, airplanes, restaurants, airports, hotels, beauty salons, post offices, docks, terminals, churches, a photography shop, stores, a print shop, schools and libraries. All participants were 18 years or older.

The level of education completed by subjects ranged from seventh grade through doctorate. There were 67 individuals with a high school education or less (average grade level, 11.64). Those with greater than a high school education (average educational level, 15.99) numbered 220. For the analyses we drew the lines between those who had up to a high school education and those who went beyond high school.

Among interviewees' occupations were office worker, manager, retiree, teacher, hotel manager, film producer, engineer, homemaker, landscaper, flight attendant, beautician, postal clerk, technician, photographer, chemist, mechanic, longshoreman, bookkeeper, printer, artist, underwriter, computer specialist, psychotherapist, auditor, cafeteria manager, consultant, buyer, fund raiser, sales/marketing manager, finance specialist, editor, graduate student, human resource manager, textile designer, actuary, writer, dental receptionist, linguist, certified public accountant, carpenter, realtor,

publisher, architect, occupational therapist, comptroller, interior designer, loan officer, dental hygienist, speech pathologist, clergy, librarian, social worker, painter, farmer, draftsman, unemployed, speech pathologist, and store owner.

Questions and resulting answers follow (key words are highlighted):

1. If you were to use a **topical** product, what would this mean to you?

Overall, 82 percent answered this correctly. Those with greater than 12th grade education: 85 percent. Those with 12th grade education or less: 73 percent. We suggest using the phrase, “product applied to the skin.”

2. If you were to use the **barrier method** for birth control, what would this involve?

Overall, only 74 percent knew this term. Greater than 12th grade education: 79 percent. Those with 12th grade or less: 58 percent. We recommend that the methods of acceptable birth control in a clinical research study be specified, and that the “barrier methods” be described (e.g., diaphragm and condom [with spermicidal], cervical cap, or sponge).

3. If you were to **waive** your rights, what does this mean?

Overall, 90 percent knew the meaning of this term. Those with greater than 12th grade education: 93 percent. Those with 12th grade or less: 81 percent. We suggest substitution of the phrase “give up” (e.g., “By signing this form I have not given up any of my legal rights.”)

4. If you were to visit a doctor, and he took a **culture**, what does this mean?

This was difficult to score. Less than 10 percent understood this term fully. To 93 percent overall it meant “taking a sample,” without the next step of processing in the laboratory, so we scored it on that basis. Those with more than high school education: 95 percent. Those with 12th grade or less: 85 percent. Because of the high understanding in the lay context without the need to go on and describe the further lab involvement, one could let this term stay as presented. However, to fully describe the process and give maximal understanding to the subject we recommend that instead of the phrase, “a culture will be taken,” they be told, “The doctor will take a sample of your blood [or skin, bone, urine, etc.] to see if any bacteria or viruses can be found in it.”

5. What does the term **efficacy** mean?

A surprise! Overall, only 33 percent knew this term. Greater than high school: 39 percent. High school or less: 13 percent. In further study we have learned that most individuals understand the term, “effectiveness.”

6. What does the term **renal** mean?

Overall, 49 percent knew the meaning of this term. Greater than 12 years education: 54 percent. High school or less: 33 percent. Obviously, the word, “kidney,” should be substituted.

7. What does the term **lactating** mean?

Overall, 78 percent understood this term. Those with greater than high school education: 83 percent. Those with high school or less: 64 percent. There was no gender difference in understanding. We prefer the term, “nursing.”

8. What does the term **gastrointestinal** mean?

Overall: 84 percent. More than high school education: 89 percent. Those with high school or less: 69 percent. If appropriate in the text we substitute “stomach and intestines.”

9. What is a **placebo**?

Another surprise! Only 75 percent of the 287 individual could define this term. Although 82 percent of those with greater than high school education knew the term, about half (52%) of those with an educational level of high school or less could explain the word. One individual thought that it “is a small animal, like an amoeba.” Substituted synonyms could be “inert substance,” “inactive preparation,” “sugar pill,” and “dummy pill.” Often we see the term “inactive drug” or “inactive medication,” which are misnomers, because a placebo is neither a drug nor medication.

10. What does **double-blind** mean?

Not so much of a surprise, but only 17 percent overall knew this term. Of those of more than high school education 21 percent could define the word. However, only 3 percent of those with high school education or less knew the term. Logically, one answer defined “double-blind” as “being blind in both eyes.” In the text we explain that double blind means that neither the subject nor the study researcher [Note that we do not call him/her the investigator!] knows what preparation the subject will be receiving. We also add the following: “However, the identity of the preparation you are taking can be rapidly determined in an emergency, if needed.”

11. What is a **vehicle preparation**?

This term was placed in the survey by the IRB, because a message had come back to them that a writer for a pharmaceutical sponsor insisted that “everyone” knew what this term meant. This turned out to be the least understood term in the survey. Only 1 of all 287 individuals could define this term. This person was in the greater than high school educational group. Some creative answers resulted in this inquiry, including the servicing of a new car by the dealer. We suggest that “placebo cream (inactive preparation)” be used. Or you may say, “In this study you will receive either the drug in the lotion or the same lotion without the drug.”

12. What is an **occult blood test**?

We have seen this in several consent forms and questioned its comprehension. Only 15 percent of the 287 individuals understood this term. In the high school or greater educational group 16 percent knew the term: in the high school or less educational group only 12 percent. One interviewee suggested it was a blood test used by witches. We suggest saying, “A sample of stool will be taken and tested for trace (or “tiny”) amounts of blood.”

13. What is **acetaminophen**?

One would think with the number of times this has been used in television advertising that “acetaminophen” would be known by many. However, overall only half (53%) the people questioned in this survey knew what acetaminophen meant. Of those who had been to college 57 percent knew the word, and only 42 percent of those who had high school or less training knew the word. We suggest, “acetaminophen, the active ingredient of Tylenol®.”

14. What is **hypertension**?

Although it did not score high, hypertension was one of the better understood terms. In fact there was virtually no difference in understanding based on educational level. Overall 69 percent knew what the word meant. In those who had been to college 69 percent knew the word, and those who had high school or less in education scored 70 percent. The obvious phrase of “high blood pressure” can be substituted.

15. What is an **electrocardiogram**?

Electrocardiogram was one of the highest scoring technical terms. Overall, 91 percent knew the meaning of the word. In those who had college training 94 percent knew the term, and 84 percent of those with high school education or less knew the term. In a younger, less-educated population, we suggest using the term, “electrocardiogram (heart test).”

16. What is a **washout period**?

Not understood well at all! Only 15 percent of the 287 individuals knew the term. There was a distinct educational difference, with 18 percent of those with college training comprehending the term, and only 6 percent of those with high school or less training knowing the meaning of the term. This should be explained in detail to the subject.

17. In the clinical research sense, what is a **protocol**?

This was an all-time favorite of the *IRB* for inclusion in the study, because it appears in over 90 percent of the consent forms that we review. However, we were even more surprised by its low scores. In the entire group only 41 percent knew the meaning of the word. In those with college training 45 percent knew the word; and only 25 percent of those with high school or less education could define the term. We substitute the terms, “study” or “study plan.”

18. If you were requested to **fast** for a period of time, what does this mean?

Not surprisingly, this was one of the all-time high scorers in the study. Overall, 92 percent knew the word, with virtually no difference in educational groups. In groups with less education, we describe what “fast” means and the required period that they will have to go without food.

19. What are the differences between **BID**, **TED**, and **QID**?

This was another surprise, but in the number of individuals who understood the terms. Overall, 24 percent comprehended the terms. The college-trained group scored 25 percent and the high school or less trained group scored 21 percent. One quick thinking individual answered that “the difference between the terms are B, T, and Q!” These terms should not be used, but the dosing should be spelled out in plain lay terms.

20. If you are using a drug **systemically**, what does this mean?

This word presented a low level of understanding with a definite educational difference! Overall, 24 percent understood the word. Those with college training scored 28 percent, but those with an educational level of high school or less scored only 10 percent. This can be described in various ways, but the phrase, “distributed throughout the body,” is usually understood.

21. If we were to tell you that your laboratory test was **negative**, what does this mean?

Because “negative” can also have a bad connotation, we decided to include this term to see if the surveyed population could tell the difference. It appears that watching all those hospital sagas on television had its positive influence. We were delighted to find that 95 percent of the overall group understood the word in this context. In the college-trained group 97 percent could interpret the term correctly. The high school or less trained group scored 88 percent.

22. If the drug you were to take was chosen **randomly**, what does this mean?

Another low scorer. Only 22 percent overall knew the word. A total of 28 percent of the college trained crowd knew the word, but only 4 percent of the high school or less trained group knew the meaning of the word. We prefer using, “by chance” or “by the flip of a coin.”

23. What is a **venipuncture**?

About half (52%) of those questioned knew the term. A small educational difference was shown with 54 percent of those with college background knowing the definition and 43 percent of those with high school level understanding the term.

We have seen descriptions of venipuncture that were so benign a subject would have difficulty realizing that a needle was going to be pushed through the skin into a vein, and it could hurt.

24. When speaking of money, what does **prorated** mean?

Surprisingly, only about one third (32%) of the surveyed population knew the word. The college group scored 36 percent and the high school group scored only 16 percent. You may bypass the confusing language by saying exactly what will happen. For example: "You will receive \$50.00 for completion of each of the sessions. If you complete all four sessions, you will receive a bonus of \$100.00; thus your total payment upon completion of the study will be \$300.00."

25. From a governmental viewpoint what is the **FDA**?

This was a difficult one to score, because only 42 percent of the surveyed population could actually come up with the words, "Food and Drug Administration." Many called it the "Federal Drug Agency." When we gave credit for the latter term, the overall group scored 90 percent. One person referred to the FDA as the "Federal Department of Agriculture," which reflects earlier history when the FDA's origins were in that agency. In consent forms we recommend that the name Food and Drug Administration be spelled out.

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