Model Volunteer Consent Forms for the Indian Health Service

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Explanation

To help investigators draft the forms needed for their projects, the IHS IRBs developed the attached 8 model volunteer forms for different hypothetical situations. The situations include 4 different research protocols typically seen in IHS, a fifth protocol typical in tertiary-care, and 2 EPI-AID protocols. The protocols, and thus the forms or sheets, range from complex (#1, #3, #5) to simple (#4, #7). The specific hypothetical situations are:

1] a randomized, double-blind, placebo-controlled, Phase III clinical trial of an Investigational New Drug vaccine, *i.e.* risk;
2] a screening by lab testing of a population for diabetes;
3] a survey about domestic violence, *i.e.*
4] a simple questionnaire survey of users of a clinic for health service needs;
5] a generic open-label single arm protocol to use and assess ribavirin for hantavirus;
6] a "youth risk behavior survey" (YRBS); and
7], 8] *information sheets*

The last page lists those elements in consent forms required by regulations 45 CFR 46 (marked by @), or needed by only some protocols (unmarked). The part of the regulation covering each element is cited. The list is from a larger checklist used by IHS Area and National IRBs.

We wrote the 6 model Volunteer Consent Forms and 2 information sheets to be understandable by most people. The National Adult Literacy Survey (NALS), whose results were released in early September, 1993, led me to revise the forms again. [1] Let me describe the NALS briefly, and show how it is relevant to consent forms.

In 1992, NALS tested a valid sample of 13,600 US adults for 3 types of applied literacy:
- *prose*
- *document*
- *quantitative*

etc.
The results of testing applied *prose*

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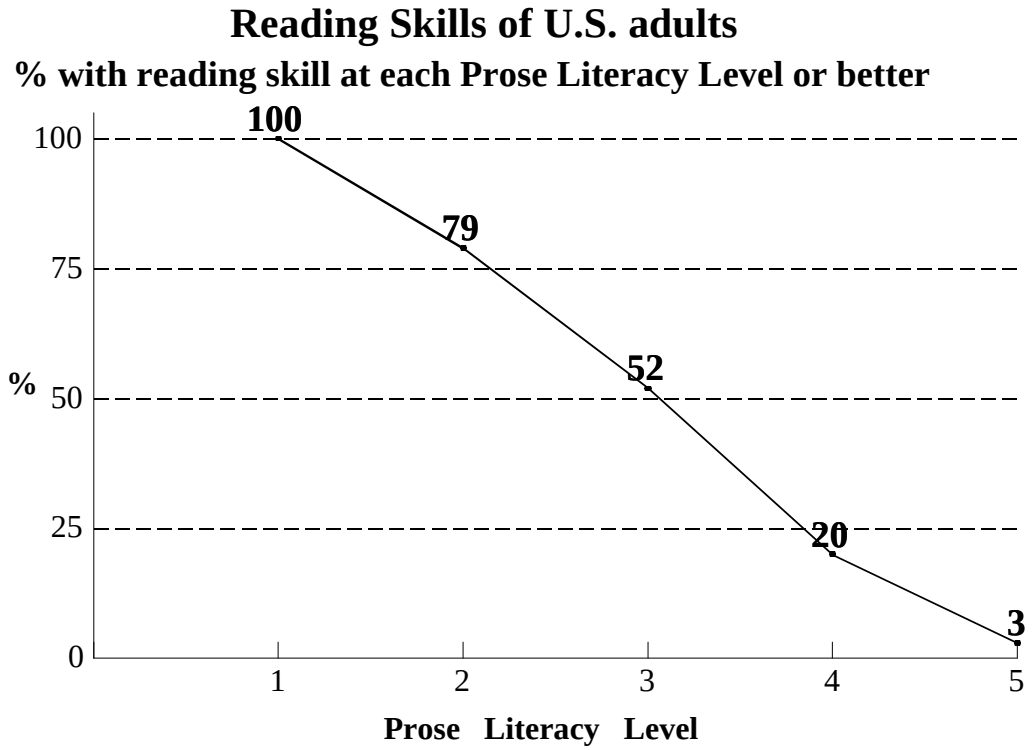
[1] Kirsch IS, Jungeblut A, Jenkins L, Kolstad A. *Adult literacy in America: a first look at the results of the National Adult Literacy Survey*. Washington, DC: National Center for Education Statistics, US Dept. Education; 1993.

NALS divided the results into 5 "Levels" of prose literacy.

- Level 1: not be able to read at all; or "read a relatively short text to locate of single piece of information."
- Level 2: "integrate two or more pieces of information to compare and contrast easily identifiable information"; locate a single piece of information but the passage had several "distractors" ("plausible but incorrect pieces of information").
- Level 3: "make matches that require low-level inferences"; "integrate information from dense or lengthy text that contains no organizational aids such as heading."
- Level 4: "integrate or synthesize information from complex or lengthy passages"; "[c]onditional information is frequently present."
- Level 5: "search for information in dense text which contains a number of plausible distractors": readers must "use specialized background knowledge" to understand part of the text.

Levels 4 and 5 describe many consent forms we have all seen, and written! How many US adults could be expected to understand Level 4 or 5 consent forms? See the graph below.



(Percentages calulated from data in the National Adult Literacy Survey.)

Apparently only 20% of US adults would understand the more dense and complex consent forms we are familiar with. How can consent forms be made understandable to more people?

One possible approach would reverse or omit those factors that contributed to decreased comprehension in the texts used by NALS. Those factors included the following.

Factors that decrease comprehension of prose material used by NALS

1.	Increase in **number of items** or categories of information
2.	Decrease in the **closeness of relationship** of the text to the information being tested
3.	Increase in **length** and **density** of the text
4.	Increase in **amount of background information needed** by reader to understand the text
5.	Increase in **number of distractors** (information apparently similar to, but actually different from, the information being tested)
6.	Decrease in the **organization aids** of the format of the text.

To reverse these factors above associated with fewer people understanding the NALS material, we drafted the Model Volunteer Consent Forms to meet the following 6 criteria.

1. Be brief, but have complete basic information. *[Affects factors 1, 2, 3.]*

The first factor cannot be eliminated entirely, because 45 CFR 46 requires more than a dozen items of information. However, omitting unnecessary or irrelevant items of information will help minimize factor 1, and help reverse factors 2 and 3.

Many potential volunteers do not read long consent forms or information sheets. The longer the form, the fewer the people who read it in its entirety, and the smaller the fraction of the form that is read by the rest. Thus, trying to be more comprehensive by adding more information may result in less information actually transmitted.

The model forms include only the *basic information*
We researchers have a bias: we tend to include too much scientific detail, and to minimize or omit some required elements of 45 CFR 46. The models are designed to counter that bias; they do not try to answer every conceivable scientific question. For example, the first model, for the experimental vaccine, does not have information about how the vaccine was made. (That would be "basic information" only if it were controversial, *e.g.*
all items required by the regulations. We tried to make the model forms include only information closely related to the core information needed to be understood, analyzed, thought over, and remembered by potential volunteers.

"Non-basic information" can be given in a separate handout, perhaps in a Question-and-Answer format. We suggest including a list of questions at the beginning of the handout, to permit people to go directly to those questions they are most interested in.

2. Be less dense, *i.e.*

All of us have encountered quite dense material that is difficult to read and to understand. Readability measures one aspect of density. Several computer programs have 1 or more readability formulas, usually expressed in school "grade" level. The readability formulas are usually a linear relationship of: the average number of words per sentence, and the average number of syllables or letters per word. Thus, a consent form with "ninth grade readability" means that the relationship between words-per-sentence and syllables-per-word of the consent form is similar to that in material read and understood by ninth graders.

Unfortunately, words-per-sentence and syllables-per-word sometimes have little to do with understandability. Rare short words in short sentences may have a mathematical similarity to material read in the lower grades, but be understood only by rare people. Beyond short words and short sentences, ways to improve readability include the following.

- Use active voice rather than passive voice verbs ("We did" rather than "It was done").
- Use common words in general.
- Make clear the links of logical sequences and of cause-and-effect, even if doing so makes the sentence much longer. ("We will do this, because that happened.")

The readability of the first model form, for the vaccine trial, is 8th grade. No sentence is 30 words or longer, while 56% are 14 words or shorter. Only 10% are in the passive voice. The text is just 1285 words, in spite of complexity of the research. Model consent #3 has 8th grade readability; model sheet #7 has 6th grade. All other models have 7th grade readability.

3. Be clear and provide the background information needed. (Use familiar terms, explain unfamiliar terms and concepts, and organize into logical sequences.) *[Affects factor #4.]*

The model forms try to omit specialty terms and concepts not essential for being informed to make a decision, and try to define and explain all new terms needed. The forms strive to be understandable, not scientifically precise. Also, people can comprehend organized new material better than unorganized new material. Thus, organizing new material into succinct blocks, and putting the blocks in a logical clear sequence, helps maximize comprehension. Writers of consent forms should ask "*hat potential volunteer's questions are does s/he not have, but needs, to understand this?*

4. Use only 1 meaning for important terms; eliminate "distractors." *[Affects factor #5.]*

Distractors include the same word with different meanings; the multiple meanings confuses people. Many consent forms have two such distractors: [1] "risk"; and [2] "benefit."

"Risk" means the *harms inherent in the research*
to come do
only in the former sense, *i.e.*
volunteers and community
"risk factors."

"Benefits" means *advantages inherent in the research*
foregone
participation
inherent possible benefits of the research for volunteers and community
services" can be used in the non-coercion disclaimer; "reimbursement" or "payment" can be used for participating.

5. Have a format that helps peoplecomprehend and rememberthe information. *[Affects factor 6.]*

Format can help people comprehend and remember complex material. Research has shown that certain elements of format help improve comprehension. Good format includes:

- Headings;
- indents;
- key words in **bold** or underlined;
- vertical lists (instead of run-on lists in long sentences);
- extra spacing between topics;
- repetition (repeat important, difficult-to-understand, points);
- reasonable-size type (not small print to minimize pages);
- lower case, NOT UPPER CASE; and
- plenty of margins and empty space in general. (Think of the daunting insurance-policy statements with their wall-to-wall and top-to-bottom writing in small print.)

These elements of format help the reader:
[A] to recognize the organization of the consent form;
[B] to recognize, know, and remember the key points; and
[C] to go back later to the form to retrieve important information, such as telephone number of the doctor to call if injury occurs.

6. Serve as a script for the face-to-face discussions with the potential volunteers. *[This criterion is not related to the above factors suggested by the NALS.]*

Face-to-face discussions between investigators and potential volunteers are the most important part of the process of informed consent. These model forms are intended to be both the **written consent forms** and the **script for the verbal explanation** by the investigators. If the verbal explanation is almost the same as the written form, each will reinforce the other and avoid inconsistency. Thus, each model is actually a combined *form-script*

One benefit is this approach is that the form-script prompts investigators to use simple language for the verbal explanation. Another benefit is that the same form-script can be used for potential volunteers who have difficulty reading, have low literacy, or need a translation--which also increases consistency of explanation among all volunteers. Investigators need develop only one form-script, not two, to permit people of all literacy levels to be potential volunteers. The form-script could also be used to videotape the explanation.

The model form-scripts reinforce both the oral discussion and visual reading. For instance, the bolded headings are the key "take home" points of the information to be transmitted. The form-script approach should result in two editorial benefits.

1] Bolded headings attract attention and are remembered. By having key points as headings, the reader more likely will remember the key points. (Bolded headings that are just titles or questions attract attention, but unfortunately are not intended to be remembered.)

2] The length is shorter. There is little or no unnecessary verbiage.

Exemplary consent forms may be necessary, but are not sufficient, for informed consent.

Researchers and IRBs should go beyond the consent form in two ways.

First, the quality of the interpersonal communication in the process of consent--the two-way sharing of information by researcher and potential volunteer--is more important that the quality of written forms. The sharing should be two-way; the researcher needs to impart information, as well as find out the level of understanding by potential subjects and elicit questions they may have. IHS IRBs have not devised ways to assure high quality in the process of communication. One way may be that the researchers, the tribal government or personnel from the tribal health department, Health Boards, and IRBs work out consent processes as partners that are culturally sensitive and respectful of each person.

Second, because some research protocols are so distant from the background information possessed by most people, the amount of totally new information required

to be in consent forms for those protocols may overwhelm even maximum clarity of writing. The generic ribavirin form, #5, may be such an example. In such circumstances, 3 added steps may help.

[1] Allow and encourage more than 24 hours for discussion and a decision. Simply having the person take the consent form home overnight can increase comprehension. [2] What people learn from written material varies by the background information they have about the subject. [3] Hence, a researcher could try to increase the background information of potential volunteers before they could understand enough to make an informed decision. *E.G.* discuss the information in 2 stages, at least a day apart. The first stage would focus on the basic information about the purpose; the second stage would summarize and answer questions about the purpose, and then focus on procedures. This approach is feasible when time is not critical, unlike the ribavirin protocol.

[2] Educate people before they are asked to participate, by publicizing and discussing the protocol repeatedly in the media. One should use as many media channels as possible, *e.g.* meetings, churches, etc. This approach is feasible when the community has high interest in the research.

[3] For one-on-one discussions with potential volunteers, use media in addition to the printed page, *e.g.* etc.

In summary, we should follow the principles of effective written communication, *i.e.* the 6 factors leading to poor comprehension. We should write consent forms understandable by 70%-80% of the adult population. Even with more than 12 important items required by 45 CFR 46, Level 2 consent forms are possible, and achievable for many research protocols. To give suggestions or comments, or to ask questions, please call or write me at:

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[2] Morrow G, Gootnick J, Schmale A. A simple technique for increasing cancer patients' knowledge of informed consent to treatment. Cancer 1978; 42:793-799.

[3] Mosenthal PB, Kirsch IS. Learning from exposition: using knowledge modeling as a basis for assessing student's knowledge. *J Reading*. 1992; 35:668-678.