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Simple Language for Assent Forms

By Stephanie Lowenhaupt

Pediatric clinical trials require the permission of a parent and assent of the child, provided the child is capable of giving informed assent. Here are some of the federal regulations that apply to assent:

> Assent means a child's affirmative agreement to participate in a clinical investigation. (21 CFR 50.3(n))
>
> In determining whether children are capable of providing assent, the IRB must take into account the ages, maturity, and psychological state of the children involved. (21 CFR 50.55(b))
>
> … the IRB must determine that adequate provisions are made for soliciting the assent of the children when, in the judgment of the IRB, the children are capable of providing assent. (21 CFR 50.55(a))
>
> The information that is given to the subject or the representative shall be in language understandable to the subject or the representative. (21 CFR 50.20)

As with informed consent forms for adult study subjects, assent forms should be understandable to pediatric study subjects. Assent forms are thus generally shorter and simpler than the permission forms given to their parents. However, many adults are less literate than many children. In fact, the parent may be less literate than his or her child, leading to the odd conclusion that the permission form should be simpler than the assent form.

There are two ways to achieve simplicity in such forms:

- Write the text at a low to moderate reading level, e.g., grade eight.
- Avoid difficult concepts that children have not learned, but with which adults are familiar. For example, adults may have more experience than children with healthcare interactions.

Potential study subjects can have very different reading and cognitive abilities, based on factors like age, education and innate capabilities. It is impractical to tailor consent, assent and permission forms for each person considering a study. (However, there could be different assent forms for children of different ages or maturities.) The person obtaining assent or consent must therefore assess comprehension and tailor the assent, consent or permission discussion accordingly.

Assent forms often leave out or greatly simplify concepts on the assumption that they will only confuse the child. In such cases, it is especially important to include this information in the permission form, so the parent, at least, receives the information.

Table 1 presents simplified language in two versions — one for adults and one for children — for 12 essential and additional elements of informed consent (21 CFR 50.25):

Table 1. Simplified Consent and Assent Language

Topic	Consent Form	Assent Form
The study involves research	This consent form provides you with information about a research study.	We want to find out how to make your sickness better.
An explanation of the purposes of the research	The purpose of this study is to find out more about diabetes treatment.	We want to find out new ways to treat diabetes.
The expected duration of the subject's participation	This study will require four visits over a 12-week period.	You will visit us four times in the next three months.
A description of the procedures to be followed	During each study visit, we will take a teaspoon of blood for testing.	During each visit, we will use a needle to get about a teaspoon full of blood.
The identification of any procedures that are experimental	All the testing in this study will be routine for patients with diabetes.	We will only do things to you that we usually do to children with your sickness.
A description of any reasonably foreseeable risks or discomforts to the subject	You may get a bruise or soreness where we take the blood sample.	You may get a sore spot from the needle.
A description of any benefits to the subject or to others that can be reasonably be expected from the research	We cannot promise that you will receive any benefit from this study. However, others with diabetes may benefit in the future.	The visits might help you, but we don't know. We might learn things that help other children.
A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject	If you choose to not be in this study, you may receive the usual treatment your doctor prescribes for your diabetes.	You don't have to come to these visits. Instead, you can go to your usual visits with your doctor.
A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained and that notes the possibility that the Food and Drug Administration may inspect records	Your study records will contain personal information about you. We will protect your identity as much as possible by storing your information in a secure area. It is possible that others may see your records, including government agencies like the FDA.	We will keep information about you secret, but we might have to share it with other people who need to see it.
For research involving more than minimal risk, an explanation of any compensation and whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information can be obtained	You will receive up to $250 for participating in this study. You will be paid $50 per visit for your time and travel and an additional $50 upon study completion. If you are injured as a result of being in this study, we have no plans to pay you. If	Your family will get up to $250 for coming to these visits. The amount will depend on how many visits you come to. If the visits make you sick, your parents will take care of you.

	you require treatment, your insurance company will be billed for any costs.	
An explanation of whom to contact for answers to pertinent questions about the research and research subjects rights, and whom to contact in the event of a research injury to the subject	If you have questions about the study, please contact the principal investigator listed on this form. For questions about your rights as a research subject, you may contact the IRB at (123) 456-5890.	If you have any questions, you can ask your parents or us.
A statement that research is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise is entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled	Participation in this study is totally voluntary. If you choose not to participate, it will not affect your relationship with your doctor. You are entitled to receive care no matter what your decision is. You may change your mind about being in the study at any time without penalty.	You do not have to come to these visits if you don't want to. You can stop coming if you want to stop.

The Flesh-Kincaid Grade Level of the text in the first column, quoted from the federal regulation, is 13.6. The grade level of the text in the second (consent) column is 8.2, a widely accepted level for adult informed consent forms. The grade level of the text in the third (assent) column is 3.6, which is exceptionally low.

The text in the consent column includes 300 words. The text in the assent column includes only 202 words, one-third fewer. All other things being equal, consent/assent forms with fewer words are more understandable. In this case, the reduction was largely achieved by leaving out or only alluding to concepts like "research study," "diabetes," "IRB" and "insurance." However, the concept of "needle" is included in the assent, but not the consent, language, on the assumption that children care a lot about needles, while adults understand that obtaining blood involves needles. Some information in the assent form, e.g., "your family will get up to $250," is intentionally vague, on the assumption that the information is best communicated in the verbal discussion. A given investigator and IRB may not agree with these assumptions for a given study; the objective here is to demonstrate how an assent form can be simplified by excluding concepts.

When attempting to write an understandable consent form for adults, it can be a useful exercise to write it for children. The above examples demonstrate that text written for an assent form can also be adapted for a consent form. For example, compare:

> We cannot promise that you will receive any benefit from this study. However, others with diabetes may benefit in the future.

with

> The visits might help you, but we don't know. We might learn things that help other children.

The assent/consent/permission process is the cornerstone of human subjects protection in clinical research, so adequate care in crafting suitable assent/consent/permission forms is well worth the effort. Table 1 demonstrates that many forms could be more understandable.

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