Research News



New consent form helps people talk about treatment options

A clinical trial is a way to find out if a new medical treatment is better or worse than current treatments. A new consent form helps people make treatment decisions.

Before joining a clinical trial, you have a right to know your options. The process of learning and choosing is called "informed consent." Here's the process:

- 1. A researcher or research nurse tells you about the risks and possible benefits of the new and unproven treatment. They'll also give you a consent form to read.
- 2. You ask questions about the clinical trial.
- 3. If you want to join, then you sign a consent form.

Many consent forms are hard to read. Sometimes people don't want to read the forms, which can be dozens of pages long. Researchers and ethicists want to make consent forms easier to understand.

Researchers from 25 transplant centers in the Blood and Marrow Clinical Trials Network (BMT CTN) tested a new consent form, compared to a standard form. They wrote both forms at an 8th-grade level. They nicknamed the new form ETRIC, short for easy-to-read informed consent.

Designed for clarity

The ETRIC form was formatted differently. Highlights included:

- Two-columns of text instead of one
- Less text on each page
- Large, simple headings
- Important information put near the beginning
- Short, direct sentences
- Familiar words instead of jargon

Researchers tested about 200 people to see how well they understood the standard form compared with ETRIC. Scores were similar for about 3 out of 4 people (77%). However, the staff and doctors said the ETRIC led to better discussions with people about their options.



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Questions to ask your doctor

If you're considering joining a clinical trial, you may want to ask:

- In plain language, please explain the risks and benefits.
- If I don't join the study, what are the risks and benefits of other treatments?

Resources for you

- <u>Read more about this research study</u>
- This research study on ClinicalTrials.gov
- <u>Get help finding clinical trials</u>

Source:

Spellecy R, Tarima S, Denzen E, et al. Easy-to-read informed consent form for hematopoietic cell transplantation clinical trials: Results from BMT CTN 1205 study. Biology of Blood and Marrow Transplantation. 2018 April 18. doi.org/10.1016/j.bbmt.2018.04.014. [Epub ahead of print]

BMT CTN Data Coordinating Center

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