A Patient's Perspective in the Informed Consent Process

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NEW CHANGES IN THE INFORMED CONSENT DOCUMENT

- -side effects are easy to find because of box structure

- -more patient centered as segments are asked as questions

- -overall flow of the document is easier to follow

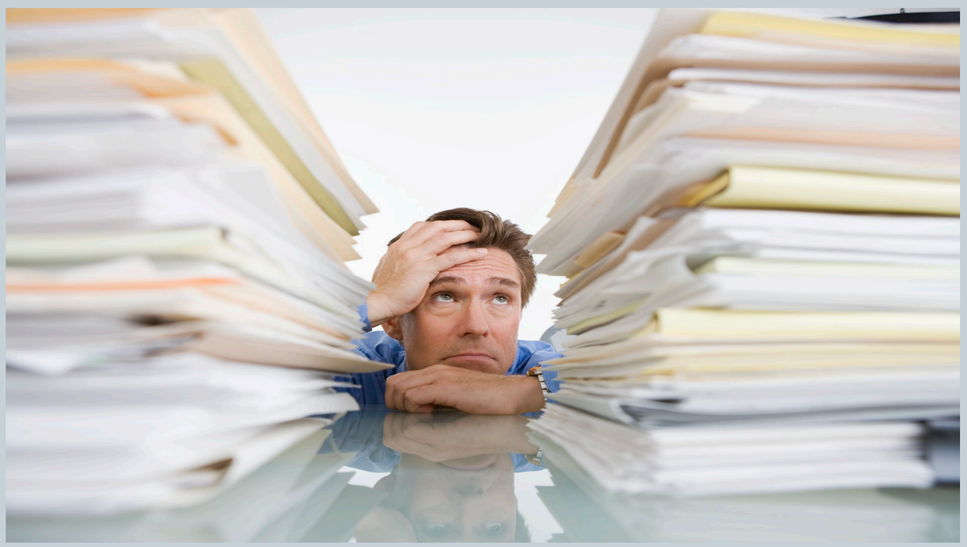
PROBLEMS REMAIN

- The document remains too long and overwhelming.
- Readability levels or simple language vary greatly, or are not used at all.
- The person reviewing the document with the potential participant varies greatly. Should there be standardized training?
- Should we check for particpant understanding?

THE PROBLEM IS DEFINED

The Problem (from NCI website)

"Many informed consent documents have become too long and complex, and do not provide a sound basis for informed decision-making."
(from working group)



Recommendations are Troublesome

"Recommendations for Specific Federally-Required Consent Elements
Purpose of the Study

The consent form should clearly and simply explain the purpose of the research study and state why the potential research participant is eligible to enroll. The main objective of the proposed study should be placed in the context of standard care. For example:

The purpose of this research study is to find out whether adding the drug Taxol to a commonly-used chemotherapy is better at preventing your cancer from coming back than the commonly-used chemotherapy by itself. The study will also see what side effects there are from adding Taxol to the commonly-used chemotherapy. Taxol has been found to be effective in treating patients with advanced breast cancer. In this study, we want to see whether Taxol will be a useful addition to the treatment of patients with early-stage breast cancer and to see if the side effects seem to be worth the possible benefit."

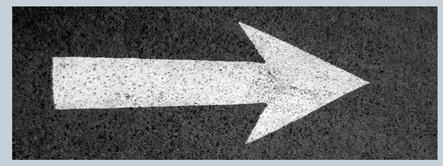
Reading levels remain too high!

Some solutions are simple

- Lexicons are out there
- Written examples are available
- Reading levels are easy to determine

  -in Microsoft Word under the “review” tab

A possible solution to aid in understanding



PAT 10101: A patient friendly summary of the consent form for potential cancer clinical trial participants-an addendum to the Informed Consent Document

What is a clinical trial?

A clinical trial is a way for scientists to find new ways of treating disease.

Sometimes a clinical trial is called a research study.

Why is this study being done?

This study is being done to measure the effects , good and bad, of a new drug along with the usual type of care for your type of cancer.

This study may or may not help you, but may help researchers find new treatments for your type of cancer.

How is this different than usual care?

- Because this drug is new, it has not been used in your type if cancer.

-The usual care for your type of cancer is this therapy and take this amount of time.

-In this clinical trial, or study, it will take more or less amount of time.

-There will be 4 more blood draws and 2 more CT scans than people treated with the usual therapy.

Costs

The cost of the usual type of treatment should be covered by you or your insurance company.

If you decide to participate in this clinical trial, the new drug will/will not be supplied by the company that makes it while you are on the study.

Calendar

What will happen when you come in each time.

Step 1	Step 2	Step 3	Step 4
			
Your weight and general health will be checked	Your blood will be drawn	We will review and update your information	You may receive treatment or have a test

Your Rights and Responsibilities

-You can choose to have comfort care without treating your cancer.

-You can choose whether or not to be a part of this clinical trial.

-You can choose to participate in the usual therapy for your type of cancer.

-If you agree to take part in the clinical trial, you can leave the study at any time.

-You must let your doctor know of any problems you are having with your care or treatment.

-If you decide to participate in this clinical trial you must read and sign the informed consent document.

Where I can I find more information?

Please contact the members of your study team if you have questions about this study or your care.

Dr. Blue 555-555-5432

Nurse Red 555-555-5678

On the web you can find additional information

www.clinicaltrials.gov

www.reputablediseasetypesite.org

The Informed Consent document your doctor gave you.

Other helpful information

You may /will want to bring someone with you to drive you home do to side effects.

You may want to bring your lunch.

You may want to bring a change of clothing.

Thank You!

- Questions?