

Patient Engagement Starts with the Informed Consent Form

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February 2025





Learning Objectives

- How can the ICF become a patient engagement tool?
- How do potential participants view consent forms?
- Changes to make the consent form more engaging.
- Practical tips for changing your consent template.
- Challenges that exist for implementing a different type of consent form.

1 INTRODUCTION

You should know some important things before you agree to be in the study. This document is called an Informed Consent Form. It will explain why we are doing the study, the possible risks and benefits, and the study procedures.

Please ask the study staff to explain any information that you do not understand. You will be asked to sign this form if you want to be in the study. You will be given a signed copy to keep.

Your participation in this study is voluntary, which means:

- You decide whether or not to join the study.
- You may decide to withdraw from the study at any time after you sign this form.
- If you decide not to join, or if you withdraw from the study, there is no penalty or loss of benefits that you normally would have.
- Your decision will not affect your medical care or treatment by doctors or by this institution.

You may qualify for this study because you have a cancer of the blood or bone marrow.

This research study involves a test drug. A test drug means the drug is not approved for the use being tested by any government office that controls new medicines. This includes the United States (US) Food and Drug Administration (FDA). In this study, the terms "ABC123" and "test drug" mean the same thing.

2 PURPOSE OF THIS STUDY

The study is trying to answer the following questions:

- What are the side effects of the test drug?
- At what dose levels are the side effects first seen?
- What is the highest dose that can be given to patients without causing severe side effects?
- How long does the test drug stay in your blood?
- Is the test drug a possible treatment for cancers of the blood or bone marrow?

3 LENGTH OF STUDY AND NUMBER OF PARTICIPANTS

The time you spend in this study receiving treatment may last up to approximately 1 year. You will have an assessment of whether you are responding to the test drug every 1 to 2 months until your cancer gets worse, you start another cancer treatment, or the study ends. If

WOULD YOU
RATHER BE
FACED WITH 20
PAGES LIKE
THIS?



or This?

Introduction

You are being asked to join a type of research called a clinical trial because you have ABC cancer or DEF cancer that has progressed during or after standard treatments. This clinical trial is being done to learn if a test drug, Cancer Treat (also known as 1234), works to treat certain cancer types and about its safety.

This document is called an Informed Consent Form. It shares important information about the trial and asks you to decide whether you want to join the trial as a research participant.

New Drug Developer is the Sponsor of this clinical trial. This means it is responsible for and pays for this trial.



Clinical trials are research studies designed to learn how a test drug or other treatment works and about its safety in people. They help doctors learn if test drugs (alone or with other treatments) are safe and if they can prevent or treat disease.

What should I do with this consent form?

- 1 **Read this entire form carefully** to help you decide if you want to join this trial. It explains why we are doing the trial, the possible risks and benefits, and the things you will be asked to do before, during, and after the trial, if you take part.
- 2 **Ask the trial staff** to explain any information you do not understand before you sign this form.
- 3 **Discuss this trial with your family, friends, and doctor** before you decide – you can take home an unsigned copy of this consent form to review with them.
- 4 **Decide if you would like to join the trial.** Being in this trial is voluntary, which means:
 - You decide whether or not to join the trial
 - You may decide to leave the trial at any time after you sign this form
 - If you decide not to join, or if you leave the trial, there is no penalty or loss of health care that you normally would have
 - Your decision will not affect your care or how your doctors or this institution treat you
- 5 **Sign and date the last pages of this form** if you agree to join the trial. You will get a copy of this signed and dated form.

What to expect during each part of the trial

1	2	3	4
Screening	Treatment	End-of-treatment visit	Follow-up
Lasts up to 28 days before you start treatment	Lasts for about 2 years with visits every 3 weeks	Within 30 days after your last dose of the test drug or the day you leave the trial	Lasts for about 6 months
You will sign this informed consent form, and then have tests. Your trial doctor will decide if you can be in the trial based on the results of the tests. If your doctor decides that you should not be in the trial, they will explain the reasons to you.	You will get the test drug every 3 weeks. Your trial doctor will do tests and check your health to learn about the safety and effects of the test drug.	After you stop taking the test drug, the trial staff will ask you questions and do tests to continue to learn about the safety and effects of the test drug.	The trial staff will contact you by phone or schedule trial visits every 12 weeks to check your health. If you stop taking the trial drug before your cancer worsens, you will have an in person visit every 12 weeks to assess your tumor status until you start a different cancer treatment, your cancer gets worse, or the trial ends.

Confidential

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✓ Costs the trial Sponsor pays for	✗ Costs the trial Sponsor does not pay for (and you may have to pay for)
The test drug and all tests and exams you get as part of this trial only.	Routine health care, such as drugs, tests and exams that you would get if you <u>are</u> not in this trial.
Emergency treatment you need if you are hurt as a direct result of participating in this trial – this does not mean that the Sponsor takes legal responsibility for the injury. If you are hurt or become ill during this trial, contact your trial doctor through their contact information provided in section 15 of this document.	Possibly, follow-up treatment after emergency treatment for an injury, even if it is due to you being hurt in this trial.
Possibly, costs of travel to the trial site, lodging, and costs for food on treatment days. Trial staff will review the repayment plan with you before you decide to join the trial.	Injuries caused by your activities of daily life that are not related to the test drug or the trial activities or costs associated with progression of your disease
	Birth control that is required during the trial



11 Privacy and personal information

Your health and trial records are personal and private.

11.1 How will my privacy be protected?

- Only your trial doctor, research staff, you, and anyone you allow have the right to look at health and research records that identify you.
- Your health and research records will be kept secret to the extent allowed by the law.
- Your research records will be identified by a code. These records will not contain information that could be used to identify you.
- Personal identifiable information from your records will not be given out without your written permission.
- You will not be identified in any papers or presentations about this trial.

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The Consent Process is a Window to the Whole Trial

- Will the trial be welcoming for me?
- Will the trial meet my needs?
- Will I feel comfortable participating?



The Consent Process is so Much More than Just Information

Engaging potential participants to participate in clinical research is a 2-way process

- Provision of information
- Questions and answers

The consent process should make potential participants:

- Knowledgeable and empowered
 - For this to happen the information must be understandable and as complete as possible
- Feel able to engage in the process and ask questions
- Able to decide to participate or not
 - Clarity on risks, benefits, alternate treatment routes and practical implications



There are many ICF Pain Points that Create Barriers and Result in Lack of Engagement

- Length of document
- Reading level sophistication
- Monotony/complexity of the document information
- Lack of visual appeal
- Publication/academic formatting
- Duplicative, too much or too little information

What do Potential Trial Participants Think of the Average Consent Form?

Boring
looking

Repetitive,
too long

It left me
with a lot of
questions

Overwhelming

Too much
jargon, too
many medical
terms

I don't like being
called a human
subject

So, What Did We Do?

Engaged a Health Literacy expert group

Goal: develop a more user-friendly informed consent document that incorporated basic and additional elements of required in all ICFs

Incorporate All the Following

Voluntary nature to participate and discontinue participation

Purpose of the research, expected duration and procedures to be followed

Reasonable and foreseeable risks and discomforts

Reasonable expected benefits

Alternative therapies and procedures

Compensation and medical treatments for research related injuries

Costs related to participation



What was the process?

- We provided the Vendor with a mock ICF based on our original template
- The Vendor re-wrote it using Health Literacy principals
 - The majority of adults struggle to access, understand and use health information
 - More than replacing jargon with simple words – although it strives for a Grade 6-7 reading level
 - Encourages people to ask questions and engage with their healthcare provider
- Reviewed by a cross-functional Sponsor team that included all groups who input into the ICF
- The feedback was incorporated into the new ICF template and there was a meeting to resolve differences of opinion between the Sponsor and the Vendor



What was the process?

- The vendor took the revised new ICF and conducted 2 virtual focus groups
 - History of cancer or a family member with cancer
 - Across racial groups
 - No prior participation in a trial or work at a Pharma company
- Feedback was shared with the Sponsor and meetings held to incorporate/reject the feedback
 - Examples of feedback were the request for color and more tables
- The revised ICF template was adopted by the Sponsor

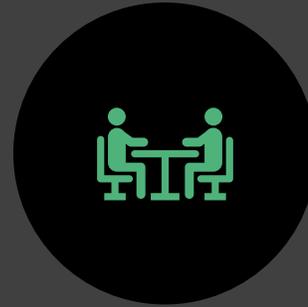
What were the challenges?



Lack of alignment on what constituted simple medical language



Needs a change in mindset to add items like a table of contents, tables and call-out boxes



It ended up longer – however feedback was that with the new format this did not concern potential participants



The Vendor proposed the use of color which we simplified so that it would still look good if it was photocopied in black and white

What did the focus group think of the new consent form?

“Well, I always believe in the KISS philosophy: keep it simple, silly. Who, what, where, how, and why. And they seem to have addressed all those here”

“I thought the words were explained very well. Like the scan that you get. They put the medical term, then the abbreviations, and then they explained it. I thought it was done very well for people who are not used to hearing those terms.”

“When I first saw it, I thought it was “bulky”. However, when I continued to read, it became more interesting because it was informative and I ended up enjoying the information it had.”

“The table of contents, color and information boxes made it easy to refer to things.”

“Thorough”

I would like to thank them very much for calling it a research participant instead of a human subject.

“I think they did address that time is a concern”

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Final Version

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Challenges

Internal (Sponsor)

- Lack of buy in can slow you down
- Lack of understanding of why we need to change
- Individuals trying to change the template once it has been agreed – you need a process for ICF template changes

External (Sites)

- Only prepared to use black and white
- Removal of the Table of Contents “because its not in our template”
- Ignoring the formatting and re-writing it in their template

Conclusion

It's possible to create a more engaging ICF

Focus Group feedback was overwhelmingly positive

We have used it in an actual trial and Advocacy Group and patient feedback was extremely positive

Sites/IRBs are not retaining all the elements



QUESTIONS