

A Health Literacy Approach to Developing Assent Templates for Pediatric Studies

*A Case Study from Eli Lilly and Company,
developed with the MRCT Center*

©MRCT Center



**MULTI-REGIONAL
CLINICAL TRIALS**

THE MRCT CENTER of
BRIGHAM AND WOMEN'S HOSPITAL
and HARVARD

Attribution

The Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard (MRCT Center) maintains the copyright to this presentation.

For any use or distribution, each slide must have the designation “© MRCT Center” and be appropriately referenced.

The Problem

Research on informed consent shows that many clinical trial participants **do not fully understand** what they are agreeing to when signing informed consent documents.

Creating **assent forms and processes** that children can understand can be even more challenging.

The Solution

As this demographic has significant limitations regarding literacy and health literacy, Eli Lilly and Company (Lilly) set out to rewrite and redesign **two current assent form templates** and the processes to use them so that they would be easy-to-use and easy-to-understand.

- One assent template was intended for **younger children ages 7–11**.
- The second assent template was intended for **older children ages 12–16**.

The Objectives

- The original and revised versions of two Child Assent Templates were assessed and **tested with the target population**.
- The goal of this research was to **improve document usability and understandability** using best practices in health communication and health literacy.
- New assent templates were to be **compatible with paper or digital use**.

Internal Lilly Partners

- Health Literacy Team
- Global ICF Team
- Global Pediatric Capabilities
- Pediatric Steering Committee
- Parent Volunteer Group

External Collaborators

- Pediatric CPM/CTM Forum
- Reproductive, Pregnancy & Pediatrics Safety Advisory Committee
- Health Research for Action (HRA), a center in the School of Public Health at UC Berkeley
- iCAN Youth Advisory Groups (iCAN) – US, Scotland, England

The Methods – Part 1

- **Writing** the original Child Assent Templates (Lilly)
- **Assessing** the original Child Assent Templates using:
 - The **Suitability Assessment of Materials (SAM)**, a validated tool to evaluate the appropriateness of materials for readers with low literacy levels (HRA)

Interpretation of SAM percentage ratings:

70 – 100% = superior material

40 – 69% = adequate material

0 – 39% = not suitable material

- **Revising** the documents (within perceived IRB constraints) for improved health literacy (HRA and Lilly)

The Methods – Part 2

- **Assessing** the revised documents via:
 - **Usability Tests** (qualitative scripted and structured interviews) of 6 healthy children to identify areas of confusion (HRA)
 - **Focus group** feedback from 3 youth advisory groups (iCAN)
- **Revising** the document based on usability tests and youth advisory group feedback (HRA and Lilly)
- **Assessing** the final documents using the SAM (HRA)
- **Providing recommendations** for improving Child Assent Templates from a health literacy perspective (HRA)

The Results

Assent Template	SAM Score (%)	Format	Pages (8 ½ x 11)	Aligns with CTTI* ?	Enables eConsent Adoption?
Older Child (original)	56% (adequate)	<ul style="list-style-type: none"> • Word document • Black and white • No illustrations • Paper 	5	No	No
Older Child (revised)	82% (superior)	<ul style="list-style-type: none"> • Booklet • Color • Photos and illustrations • Paper or digital with e-signature option 	4	Yes	Yes
Younger Child (original)	50% (adequate)	<ul style="list-style-type: none"> • Word document • Black and white • Clip art • Paper 	11	No	No
Younger Child (revised)	83% (superior)	<ul style="list-style-type: none"> • Story book • Color • Comic book style illustrations • Paper or digital with e-signature option 	9	Yes	Yes

* Clinical Trials Transformation Initiative

CTTI is a US public private partnership committed to improving clinical trials via recommendations that align with trends and federal requirements. The health literate assents were developed to be in alignment with CTTI informed consent guidance.

Younger Child Assent

Before



The doctor has told you that you are sick and you have an illness called **XXXX**.

We are asking if you will let us look at you to see if this medicine called **XXXX** will help you.

We want to learn more about this medicine. We also want to know if it can help other children with **XXXXX** too.

Children with **XXXX** (*Instructions: Insert a simple explanation of the disease issues; an example for ADHD, "a hard time sitting still and doing their school work."*)

After



Script

Both doctors then told Hannah and Michael the same thing. They said:

"You don't have to say yes. And no one, including your parents, will be upset if you say no. And if you do say yes, you can stop at any time.

So do you want to be in the study? If so, you can sign your name or just say yes."

You can swipe the screen now.

Older Child Assent

Before

OLDER CHILD ASSENT FORM			
Study Alias:	XXX-XX-XXXX	Age Covered:	XX to XX Years

[Instructions: Update the study alias and the ages covered by the assent above. It is acceptable to add the sponsor and/or investigator name to the table above. Add study alias and version date to footer. Delete first page.]

Information and Assent Form for Minors

You might not know what some of these words mean. Please ask the study doctor or the study staff to explain any words or information that do not make sense to you. You may take home a copy of this assent form to think about or discuss with family or friends before making your decision.

Will you be a part of this research study?

We are asking you and about [number of subjects] other children to be in our research study. This study will help us learn more about a study drug called [insert name of study drug]. [insert name of study drug] that is being tested to find out if it helps children who have a medical condition called [insert name of condition]. The study drug is also being tested to find out what other effects, sometimes called "side effects," this drug might have for the children who take it.

Children who have [insert name of condition] often have [description of symptoms]. We are asking you to be a part of this study because your doctor has determined you have [insert name of condition].

In order to be a part of this study, you and your parent (or legal guardian) must listen to someone from your doctor's office explain the information about this study, and you should ask any questions that you have. Then, in order for you to start the study, your parent or your legal guardian must agree, in writing, that you will take part. Also, if you agree to take part, you must sign this form at the end to show that you want to be in the study. If you decide to take part in this study, and then change your mind, you may choose to stop at any time.

Do you need to be in this study to be treated?

Being in this study is your choice and the choice of your parent or guardian. You do not have to be in this study to be treated for your medical condition. There are other ways of treating your condition that your doctor can tell you about.

After

The Verina Research Study

This booklet will tell you about a research study on Verina, a medicine to treat your condition. You and your parents might decide to be part of this study. This booklet will help you decide.



What will this research study do?

This study will help us learn more about a medicine called Verina. We are testing this medicine to find out if it helps children who have cancer. We also want to find out if this medicine causes any unwanted reactions. Unwanted reactions are usually called side effects.

Who will this study help?

Will it help me?

Taking part in the study could make you feel better. It also could make you feel worse, or the same.

Will it help other kids?

The study might help other young people, if this study shows that the study medicine works and is safe to use, then more children may be able to take it.

Ask questions.

Before you decide, you can ask us anything you want. For example, if there is a word you do not know, you can ask what it means. You can also ask about how you might feel during the study.



Why should I read this booklet?

This booklet explains what a study is, and what it will be like to be in the study. If you want to take part, you can sign the form at the end of this booklet or just say yes. Your parents will also sign a form that says they consent to you being in the study.

You can change your mind.

If you choose to be in this study, you can always change your mind later. This means you can stop being in the study at any time. You do not have to be in the study at all if you do not want to.

Lessons Learned

- Youth appreciated the effort to structure the assent in ways they could **read and understand** the information.
- **Colorful photographs and images** helped to make the assent less intimidating and provided natural breaks in reading that aid comprehension.
- Youth thought it was very important to understand **who will benefit from the study**.
- Youth wanted to know what to expect if they choose to participate including **what will happen and how often**.
- Youth **wanted to be thanked** for considering participation even if they decline a study.

Recommendations

When developing pediatric clinical trial materials:

- **Integrate** health literacy principles
- **Assess** readability with the SAM (or other validated tool)
- **Conduct** usability testing with Youth Advisory Groups

Links & Resources

Suitability Assessment of Materials (SAM)

<http://aspiruslibrary.org/literacy/sam.pdf>

MRCT Center Health Literacy in Clinical Research Consent Information

<https://mrctcenter.org/health-literacy/trail-life-cycle/overview/consent/>

MRCT Center Health Literacy in Clinical Research “Tools”

<https://mrctcenter.org/health-literacy/tools/overview/>