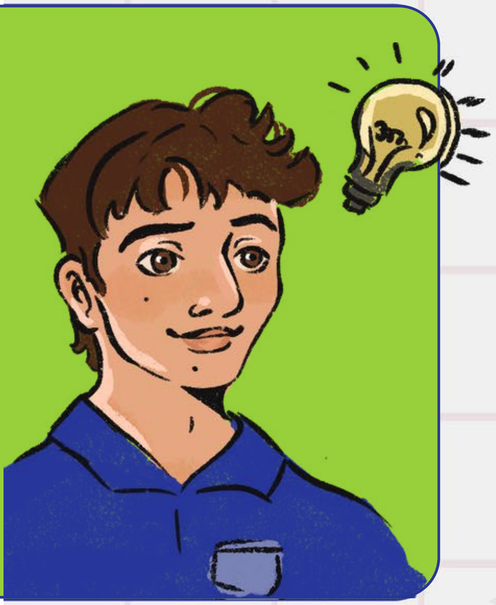
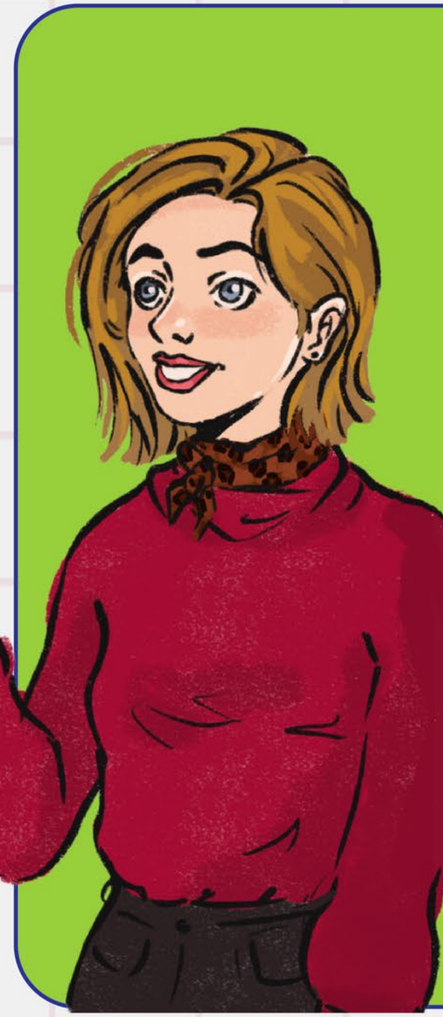
ICAN x MRCT MULTI-REGIONAL CLINICAL TRIALS
THE MRCT CENTER OF BRIGHAM AND WOMEN'S HOSPITAL and HARVARD

Understanding Clinical Trials



LESSON ONE



Acknowledgements

Sabina Goldstein-Becerra
Executive Director, iCAN
- Creator of Curriculum

Sylvia Baedorf Kassis
Program Director, MRCT Center
- Curriculum Advisor

Abby Clark
Director of Operations, iCAN
- Designer and Illustrator of Curriculum

Kayleigh To
Program Manager, MRCT Center
- Curriculum Advisor

Special thanks to the KIDS Curriculum Steering Committee:
- Anvita, KIDS CHOC; Joey, KIDS Rainbow; Meghan, KIDS Virtual

Month One

Objectives

- Understand the purpose of clinical trials
- Learn why clear language in research matters
- Explore and apply the MRCT Center's Clinical Research Glossary

What is a Clinical Trial? & Intro to the MRCT Center's Clinical Research Glossary

Ages 11–14 | Duration: ~180 minutes

Ok

Created with the MRCT Center, iCAN Leadership, and iCAN Youth Members: Meghan, Anvita, and Joey

Agenda

1. What Are Clinical Trials and Why They Matter
2. How Clinical Trials Connect to Real Life
3. Stories from Kids Who Joined a Clinical Trial: Lindsay, Inaaya, and Berkley
4. Using Language
5. Looking at an Assent Form
6. Fun Game Time: Jeopardy, Word Game, or Both!
7. Thinking About What We Learned

What is a clinical Trial?

A clinical trial is a research study that tests drugs, devices, and treatments to see if they are safe and work in people.

MRCT Center - Clinical Research Glossary https://mrctcenter.org/glossaryterm/clinical-trial/

Most medicines, vaccines, and devices we use today were once part of a clinical trial.

Warm Up:

What comes to mind when you hear the words “clinical trial”?

- Create a word cloud or collect ideas on a whiteboard.
- Encourage short answers like: medicine, research, testing, patients.
- Transition: "Let’s see how close your ideas are to how researchers describe clinical trials."

Why Clinical Trials Exist

Glossary intro for iCAN curriculum

MRCT intro for iCAN curriculum

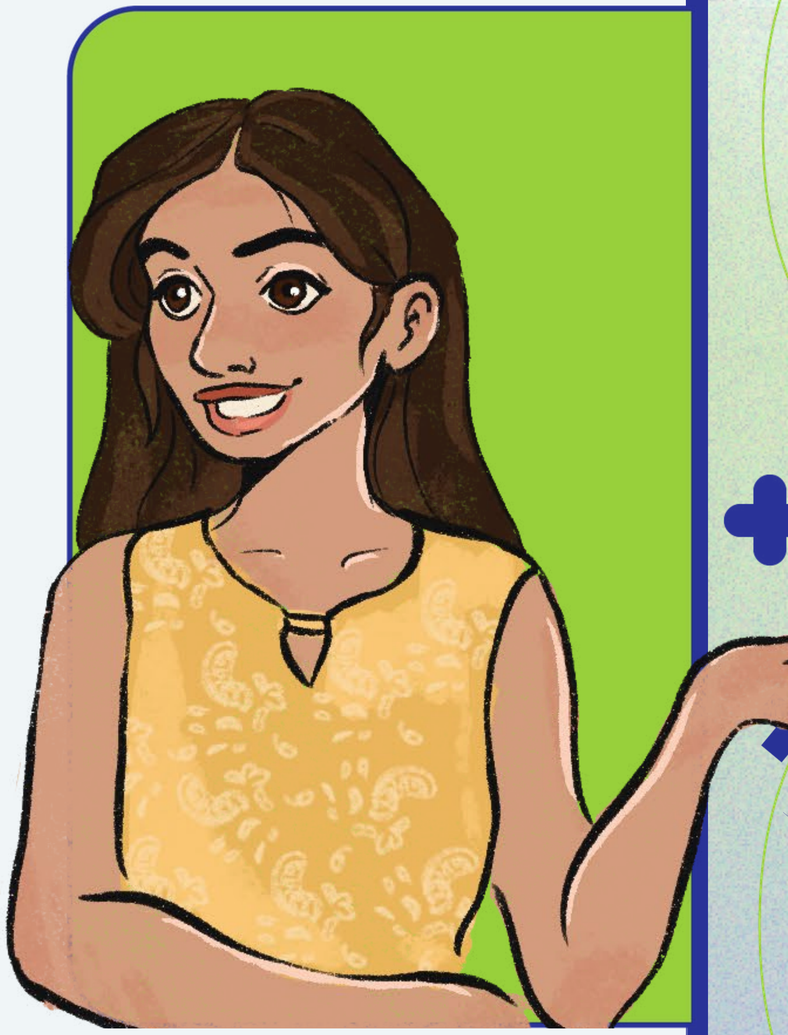
Ask Kids:

Why do you think clinical trials are important?

Real-Life Clinical Trial Experiences

- Has anyone here ever participated in a clinical trial, or do you know someone who has?
- If so, what was that experience like?
- What made you (or them) decide to join, and what did you learn from it?

We are going to read some examples and stories from real iCAN KIDS who have taken part in clinical trials, sharing what it was really like, what they learned, and how it helped them and others. Please note that the stories reflect real, first-hand narratives and may not cover all of the details of a clinical trial experience.

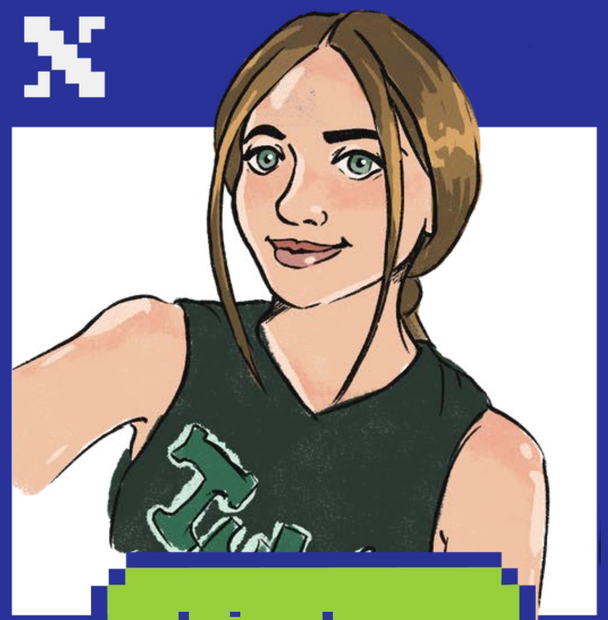


Lindsay's Story

Your Health Story:

- **What condition or illness are (were) you living with?**
  - Epilepsy (Jeavons Syndrome)
- **How did it affect your life before the clinical trial?**
  - The clinical trial I participated in wasn't for epilepsy, it was for a COVID-19 vaccine, but I enrolled because I wanted to help with scientific discovery to help our community during the pandemic.

Age: 19
Home Town: San Diego, CA
Fun Fact: I play acoustic, electric, and bass guitar



Lindsay

Lindsay's Story

Your Clinical Trial Experience:

- **What kinds of visits, tests, or treatments did you have?**
  - I had an initial visit when I signed explaining the consent form that explained what was going to happen in the trial. At the next appointment I received the study intervention, which was either the vaccine or placebo (double-blind). After that I had regular monthly appointments to get my blood drawn, COVID test, etc.
- **What surprised you?**
  - How simple and easy the process was!
- **One positive experience**
  - I felt good knowing I had potentially helped other people who contracted COVID. When I later contracted COVID a year later I felt safe knowing the vaccine would prevent me from having severe symptoms.
- **One challenging moment (if comfortable sharing)**
  - As someone with a fear of blood, the consistent blood draws was something that I didn't necessarily look forward to. It made me quite uneasy and very nervous every single appointment, but the clinical study staff were very supportive and made it seem easy.

Lindsay's Story

Why You Joined a Clinical Trial?

- **How did you learn about the trial?**
  - I learned about it from my parents who participated in a similar trial for the Pfizer COVID-19 vaccine
- **What made you or your family decide to participate?**
  - We decided to participate because COVID-19 was something we saw impacting many people in different ways. I wanted to do whatever I could do to contribute to research to help find a safe vaccine that would prevent further severe cases or even death. I just really wanted to be part of the solution to end the pandemic and save lives.

What You Learned:

- **How did the trial help you?**
  - It actually helped with my uneasiness around needles and blood!
- **What did you learn about yourself or about research?**
  - That I can accomplish anything no matter how scary it may seem. I also learned just how intricate the clinical research process is in order to get accurate results. I also learned how precise and comprehensive the consent process is for participants which reinforced the ethics of clinical trials for me.

Lindsay's Story

Your Message to Other Kids:

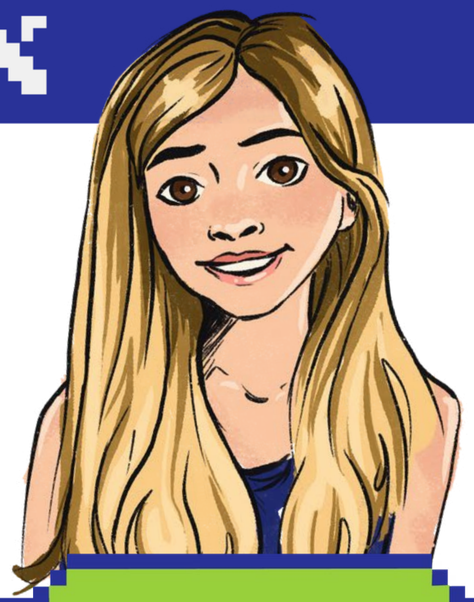
- **Any advice for kids who are nervous about clinical trials?**
  - By participating in a clinical trial you are helping kids whom you have never met, but your participation does so much for helping other kids and people just like you.
- **What do you want doctors or researchers to know about working with kids?**
  - I want them to know that kids will be nervous. They may not also understand the extent of what we are going through, but that doesn't mean we don't want to help science.
  - We just want everything explained to us in a way that we will understand even if it is our parent/adult guardian that are consenting.
  - It is important for researchers to be able to tailor their explanations to their audience of participants, the kids, and to be patient and answer all questions. And don't forget to be supportive if they are scared.

Berkley's Story

Your Health Story:

- **What condition or illness are (were) you living with?**
  - The conditions I live with are stroke in utero, hydrocephalus, and a connective tissue disorder. It has always been hard for me to walk, and this clinical trial made walking easier.

Age: 16
Home Town: Chicago, IL
Fun Fact: I love reading.



Berkley

Why You Joined a Clinical Trial:

- Shirley, Ryan, and AbilityLab asked me because they know me and my story. I decided to participate because the trial device could benefit me if it got approved.

Berkley's Story

Your Clinical Trial Experience

- **What kinds of visits, tests, or treatments did you have?**
  - This was all done in one visit. It was a walking study, which meant I walked on a treadmill for a certain amount of time without the device. Then I took a break, they put on the device, and I walked on the treadmill for the same amount of time—but this time with the device.
  - I also had electrodes placed on my legs to monitor and trigger movements while walking with and without the device.
  - This helped the researchers see how the device responded to different leg movements and how it helped in those areas.I was surprised by how much the device actually helped me. One positive thing about this trial was being able to see the future of this device and how it could help people like me walk.

Berkley's Story

What You Learned:

- The trial helped me because it was easier to walk with the device during the treadmill intervals. I learned that the research process is extensive when it comes to devices like this.

Your Message to Other Kids:

- I would say to do the clinical trial if you feel comfortable because you never know how it could help you. One thing I want doctors to know is that we are very capable of doing hard things.

Let's Break It Down

Let's Talk About These Clinical Trial Experiences:

- Spot the similarities and differences:
  - Did any of the stories feel similar to each other?
  - How were some experiences different?

What Stood Out to You?

- Was there a part of someone's story that really caught your attention or surprised you?

Feelings & Challenges:

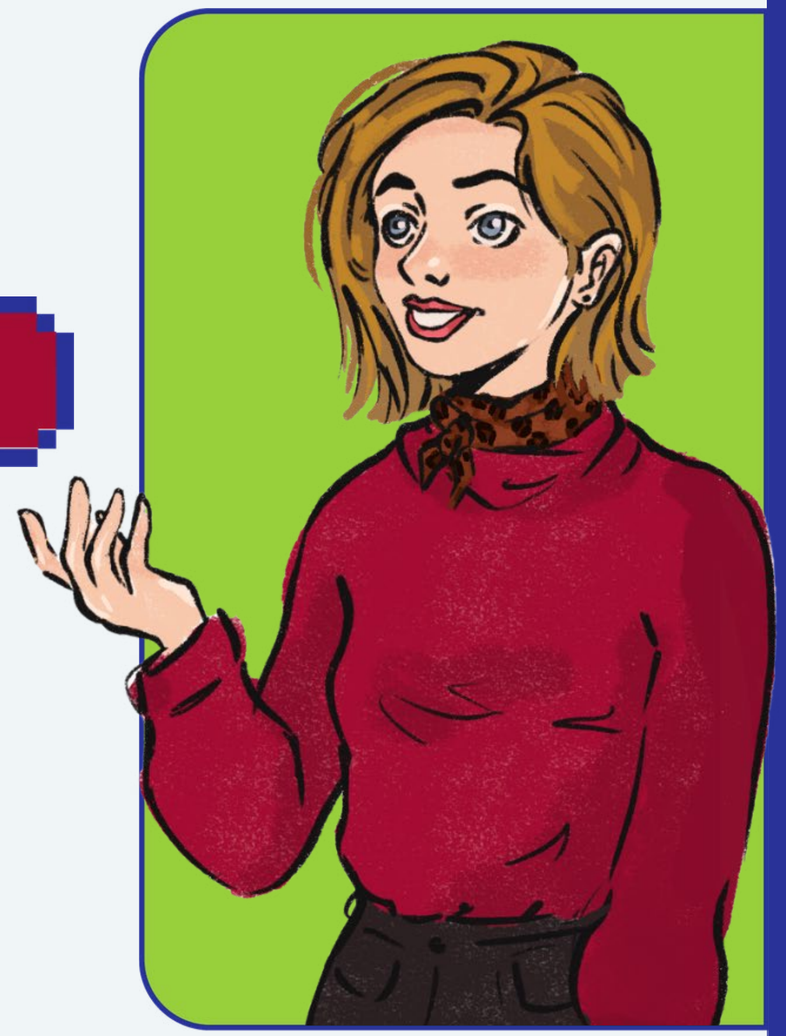
- What do you think it was like to go through a clinical trial?
- What do you imagine was hard or scary, and what might have been exciting?

What We Can Learn:

- What do these stories teach us about why kids participate in clinical trials?
- How could what we learned help other kids or families who might be thinking about joining one?

Your Thoughts:

- Would you participate in a clinical trial?
- Why or why not?



The Importance of Plain Language

- The foundation of ethical clinical trials is making sure participants go through an informed consent process and have a chance to ask questions.
- To help people truly understand the consent/assent form, it's best to provide information that is easy to understand the first time someone reads or hears it. That's what plain language is!

Check out the next slide for a real-life example!

Why do you think plain language matters so much?

Why Clear Plain Language Matters:

TITLE: Winship 2176-11: Omacetaxine for Consolidation and Maintenance in Patients Age ≥ 55 with AML in First Remission: a Pilot Study

PRINCIPAL INVESTIGATOR: Martha Arellano, MD

STUDY SPONSOR: Martha Arellano, MD

STUDY SUPPORTER: Teva Pharmaceuticals

INTRODUCTION

You are being asked to be in a medical research study. This form is designed to tell you everything you need to think about before you decide to consent (agree) to be in the study or not to be in the study. **It is entirely your choice. If you decide to take part, you can change your mind later on and withdraw from the research study.** The decision to join or not join the research study will not cause you to lose any medical benefits. If you decide not to take part in this study, your doctor will continue to treat you.

Before making your decision:

- Please carefully read this form or have it read to you
- Please listen to the study doctor or study staff explain the study to you
- Please ask questions about anything that is not clear

You will be given a copy of this consent form, to keep. Feel free to take your time thinking about whether you would like to take part in this study. You may wish to discuss your decision with family or friends. Do not sign this consent form unless you have had a chance to ask questions and get answers that make sense to you. By signing this form you will not give up any legal rights.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. law. This Web site will not include information that can identify you. At most the Web site will include a summary of the results. You may search this Web site at any time.

WHY IS THIS STUDY BEING DONE?

You are being asked to take part in this trial because you have Acute Myelogenous Leukemia (AML) and have been determined to be a candidate for our institutional standard induction chemotherapy regimen. The standard treatment of AML is clear for younger patients and includes receiving induction and consolidation chemotherapy. However, for older patients with AML, there is no standard therapy that is agreed upon by all doctors. Induction chemotherapy is the initial chemotherapy designed to achieve a remission that is to get rid of the AML cells that can be detected in the blood

Directions:

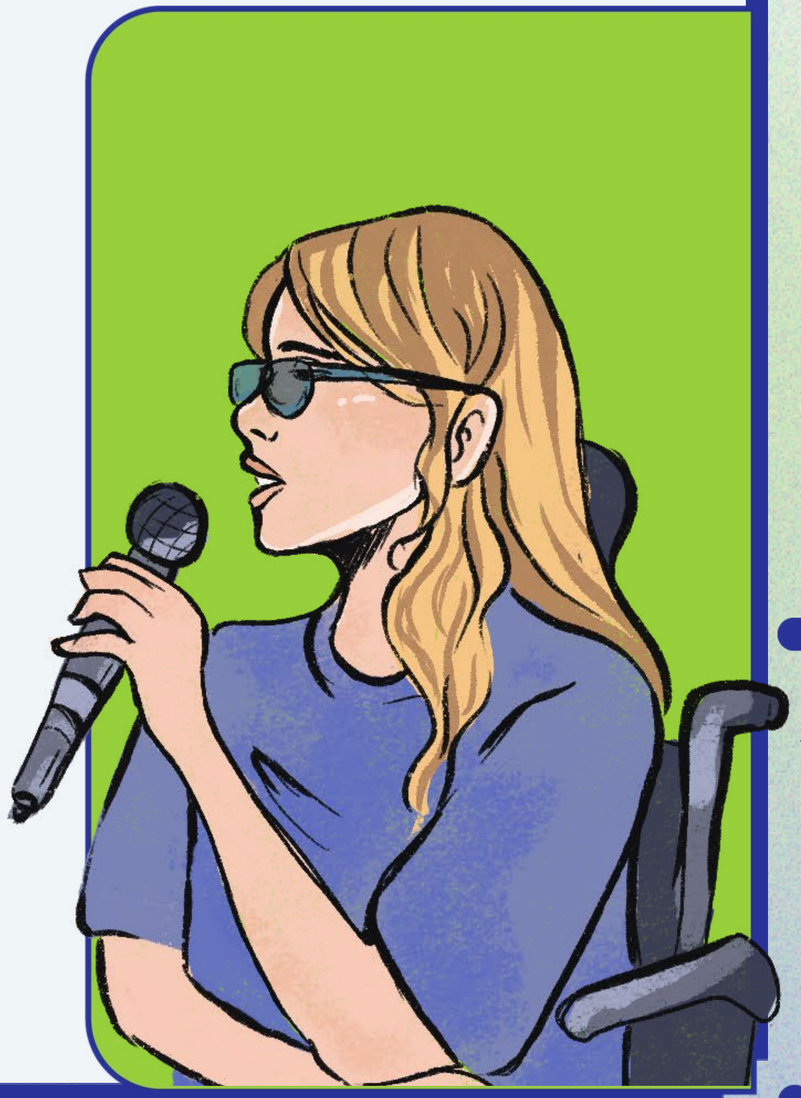
- Work Together or Independently: Review the Document (as much as you can get through)
- Ask: Which words are confusing?

Full Sample Consent Form:

- **https://drive.google.com/file/d/1asmhNdnLDjkKVf30NSTMo7orVNbu3BOj/view?usp=sharing**

Why Using Plain Language Matters

- **Builds trust:** Kids feel respected when the information is easy to understand.
- **Makes things clear:** Complicated medical ideas are easier to follow.
- **Reduces worry:** Knowing what's happening helps kids feel calm.
- **Helps make good choices:** Clear info helps participants decide what's best for them.
- **Supports participation:** Easy-to-understand materials make joining research less confusing and increases patients willingness to participate and stay in the study.



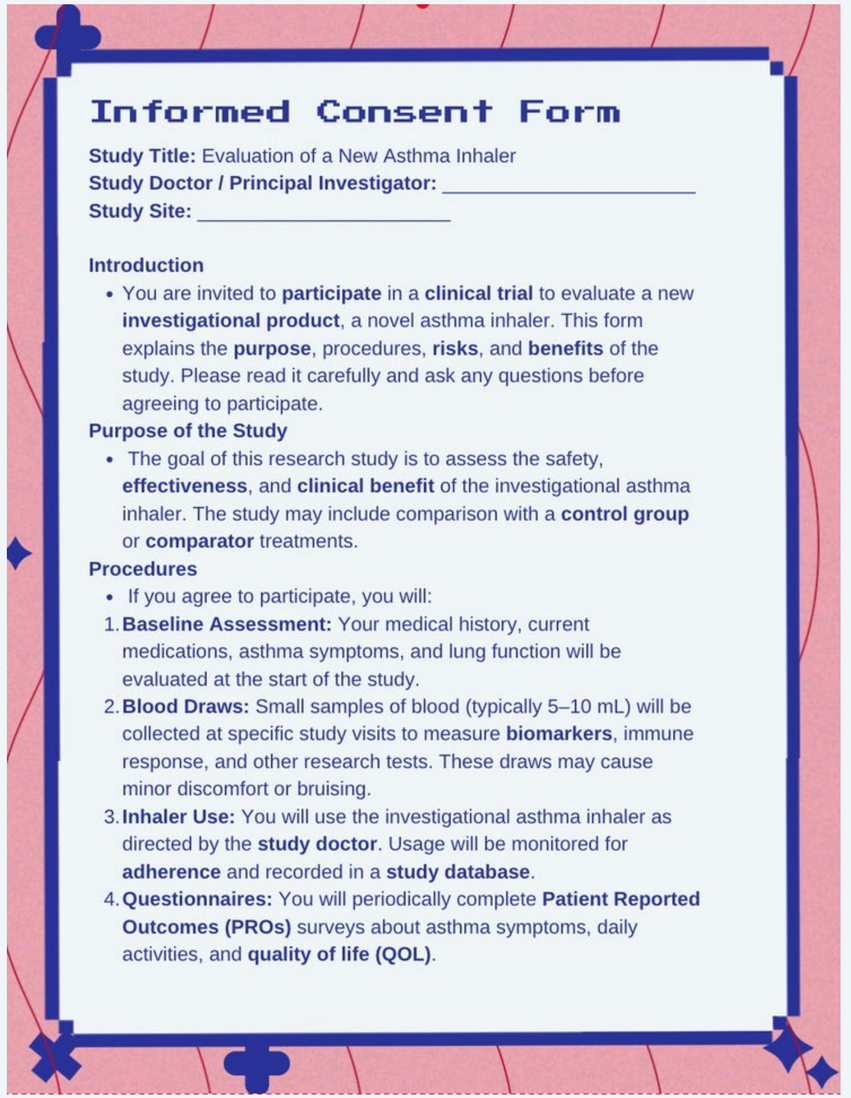
MRCT Glossary Exploration

Directions:

- Kids use the MRCT Center's Clinical Research Glossary to identify terms in a sample informed consent form.

Use this website to define the bolded terms: https://mrctcenter.org/glossary/

Download Here...



Informed Consent Form

Study Title: Evaluation of a New Asthma Inhaler
Study Doctor / Principal Investigator: _____
Study Site: _____

Introduction

- You are invited to **participate** in a **clinical trial** to evaluate a new **investigational product**, a novel asthma inhaler. This form explains the **purpose**, procedures, **risks**, and **benefits** of the study. Please read it carefully and ask any questions before agreeing to participate.

Purpose of the Study

- The goal of this research study is to assess the safety, **effectiveness**, and **clinical benefit** of the investigational asthma inhaler. The study may include comparison with a **control group** or **comparator** treatments.

Procedures

- If you agree to participate, you will:

1. **Baseline Assessment:** Your medical history, current medications, asthma symptoms, and lung function will be evaluated at the start of the study.
2. **Blood Draws:** Small samples of blood (typically 5–10 mL) will be collected at specific study visits to measure **biomarkers**, immune response, and other research tests. These draws may cause minor discomfort or bruising.
3. **Inhaler Use:** You will use the investigational asthma inhaler as directed by the **study doctor**. Usage will be monitored for **adherence** and recorded in a **study database**.
4. **Questionnaires:** You will periodically complete **Patient Reported Outcomes (PROs)** surveys about asthma symptoms, daily activities, and **quality of life (QOL)**.

Jeopardy Game: Research Term

How to Play Jeopardy:

- **Goal:**
  - Have fun and see how much you know! The team with the most points at the end wins.
- **Here's How It Works:**
  - The game board has categories at the top, like Introduction, Purpose of Study, Procedures, and More!
  - Under each category are questions worth points — 100, 200, 300, and so on.
- **Playing the Game:**

1. One team picks a category and point value.
   a. Example: "We'll take *Purpose of Study* for 200!"
2. The host reads the question. Remember, in Jeopardy, the question is actually the answer, so you respond in the form of a question.
   a. Example:
      i. Host says: "This is the group of people who take part in a clinical trial."
      ii. Your team answers: "What are participants?"
3. If you're right, you earn those points and get to pick the next question.
4. If you're wrong, another team gets a chance to answer.

Jeopardy Game: Research Term Cont.

Directions Cont.:

Final Jeopardy:

- At the end, there's one big question. Teams can wager points before seeing it.
  - Write down your answer.
  - Reveal the correct response.
  - You gain or lose the points you wagered depending on whether you got it right.

Winning:

- The team with the most points at the end wins, and bragging rights, of course!

Play Here...

Wordle Challenge

How to Play Wordle:

- **Goal:**
  - Figure out the hidden letter word in 6 tries or less!
- **Here's How It Works:**

1. **Take your first guess**
   a. Type anyword and hit enter.
2. **Look at the colors:**
   a. Green: The letter is in the right spot!
   b. Yellow: The letter is in the word, but needs to move.
   c. Gray: This letter isn't in the word at all.
3. **Use the Clues**
   a. Each guess gives you hints. Pay attention to the colors to help with your next try.
4. **Keep Guessing**
   a. You have 6 guesses to find the hidden word.
   b. Try new words and move letters around based on what you've learned.

Tips:

- Start with words that have common letters like A, E, R, S, or T.
- Keep letters that turn green in the same spot!
- Skip letters that turn gray — they won't appear in the word.

Winning:

- Guess the word in 6 tries or fewer? You're a Wordle champ!
- Can't get it this time? No worries; the word will be revealed, and you can try again tomorrow or with a new word.

Reflections & Wrap-Up

Discussion Prompts

- Why is using plain language in research important?
- Which new term stood out to you most today?

How to find a clinical trial: Start With Reliable Search Tools

ClinicalTrials.gov (U.S. & International)

- The largest and most up-to-date database.
- Use filters for age, condition, study type, and distance.
- Look for the “Contacts and Locations” section to ask about accessibility needs.

ResearchMatch.org

- A free, secure registry that connects volunteers with researchers.
- Good for families who want researchers to reach *them*.

CenterWatch

- User-friendly site with detailed study descriptions and email alerts.

Patient Advocacy Groups

- (often best for rare/complex conditions)
- Many condition-specific orgs run or track clinical trials:
- iCAN members often hear about pediatric trials early.
- CP Strong, NORD, Global Genes, Cure Duchenne, etc.
- These groups know the most family-friendly and accessible trial sites.