INFORMED CONSENT:

BEING THE PARTICIPANT ADVOCATE

JTF Competencies: 2, 4, 8

SKILLED LEVEL

RESEARCH PROFESSIONALS NETWORK

FEBRUARY 26, 2026

1

PRESENTERS

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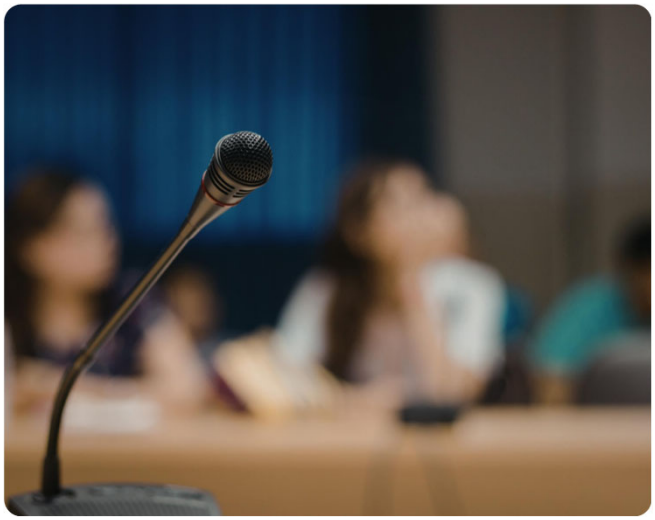

RESEARCH PROFESSIONALS NETWORK

2

WORKSHOP OVERVIEW

- Practical skills to conduct informed consent, protecting participant rights and voluntary decision-making
- Ethical/regulatory principles and clear communication strategies
- Tailor consent to participants' needs
- Practice real-world scenarios & participant-centered tools

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3

OBJECTIVES

1. APPLY ETHICAL & REGULATORY PRINCIPLES TO DESIGN INFORMED CONSENT PROCESSES THAT PROTECT PARTICIPANT RIGHTS & PROMOTE VOLUNTARINESS.

1. IDENTIFY EFFECTIVE COMMUNICATION STRATEGIES TO ENSURE PARTICIPANTS CLEARLY UNDERSTAND STUDY PURPOSES, PROCEDURES, RISKS, & BENEFITS.

1. UNDERSTAND HOW TO TAILOR CONSENT APPROACHES TO SUPPORT PARTICIPANTS' FUNCTIONAL NEEDS AND PREFERENCES, ENSURING ACCESSIBILITY AND MEANINGFUL COMPREHENSION.

4

SCENARIO

CONSENTING A POTENTIAL PARTICIPANT

What Not To Do // Informed Consent Training

5

RESEARCH PROFESSIONALS NETWORK

SCENARIO DISCUSSION

INFORMED CONSENT

Rate how this conversation went
(1 = Worst - 5 = Best).

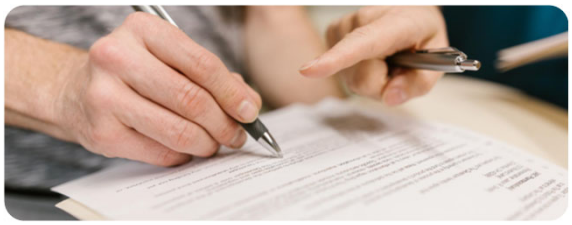
In the Chat (or unmute):

- **What issues/gaps did you observe?**
- **Would you sign up for a study after that conversation?**

6

We are trained on the basics…

Required Consent Elements & What the Regs Say…



General R.

- Legally obtain consent
- Non-coercive
- Understandable language
- Informed discussion
- Reasons for participation
- Rights & liability

Elements of Consent

- Research
- Risks
- Benefits
- Alternative
- Confidentiality
- Research-Related Injury
- Contact
- Voluntary

SCAN ME

FDA 21 CFR 50.25

SCAN ME

45 CFR 46

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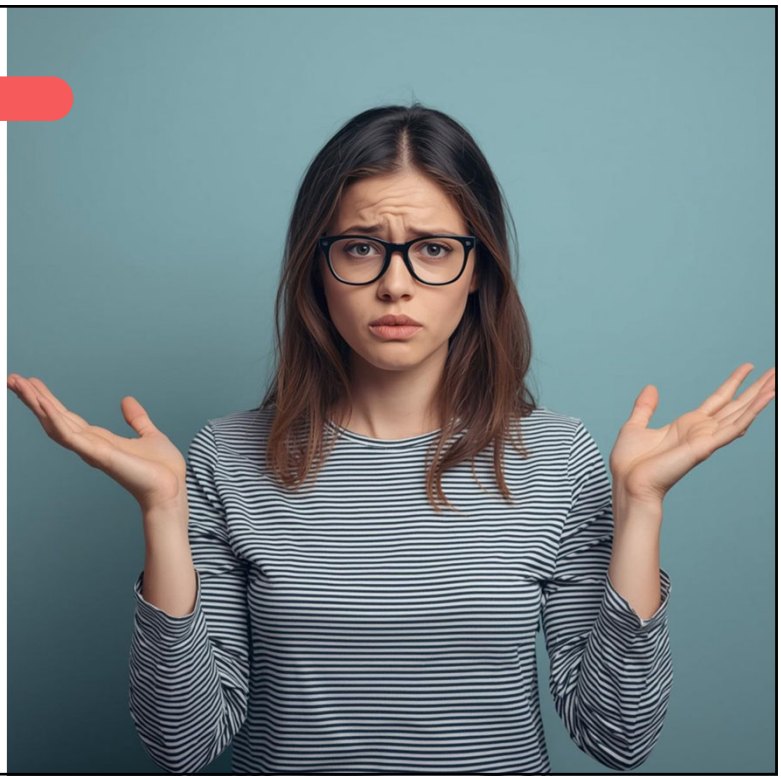
The Problem

…SO WHY SHOULD WE CARE?



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The History

History Shows Us What Happens When Research Is Conducted Without Safeguards

- Dr. Henry Beecher's 1966 article exposed 22 unethical studies
- Participants were exposed to serious risks with no potential benefit

"ADMINISTERED RISKY DRUGS"
"WITHHELD EFFECTIVE TREATMENTS"
"EXPOSED PEOPLE TO DISEASES"

"It's for science!"

SCAN HERE

Henry Beecher's Contributions to the Ethics of Clinical Research

Relying solely on 'good' or 'conscientious' investigators is not enough. Ethical protections must be built into the system.

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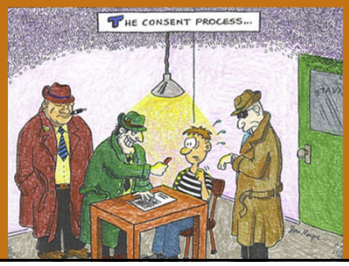
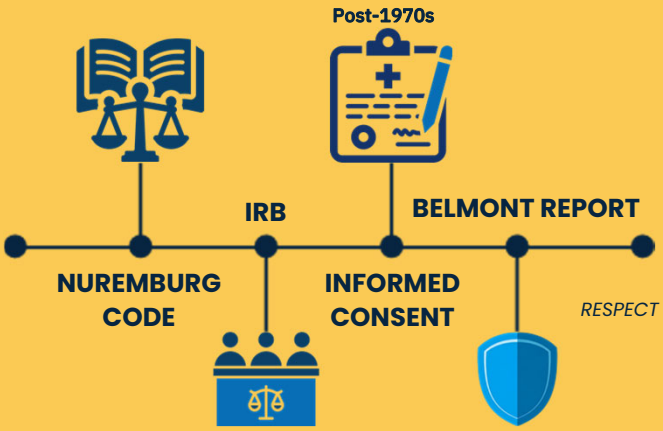
Before Modern Ethics

Pre-1970s



Why It Matters

Today's Protections:



EVERYTHING WE HAVE TODAY (IRBS, REGULATIONS, INFORMED CONSENT, PARTICIPANT PROTECTIONS) **EXISTS BECAUSE PARTICIPANTS WERE HARMED.**

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Ongoing Challenges

Didn't end in the 1960s. Ethical challenges are still happening.

Including:

- Hidden genetic risks
- Data misuse
- Pressure to enroll
- "Research participation"

INFORMED CONSENT ISN'T A ONE-TIME SIGNATURE.
IT'S AN ONGOING CONVERSATION.

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That's why **Clinical Research Professionals are so critical.**

Every interaction we have is part of the safeguard system meant to protect people from the mistakes of the past-and from the risks of today.

"Every patient [or participant] should be a full partner in decision-making."
-Toni Cordell

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Why are Participants Confused?

Low Numeracy

Low Literacy

Confusion about the Purpose of Consent Process

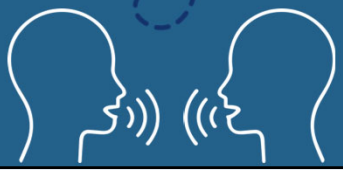
Limited English Proficiency

Time Pressures
Noise Fatigue

Cultural Dissonance

Cognitive Impairments
Neurodivergence

In Pain or Distracted



National Assessment of Adult Literacy (NAAL)

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Why Health Literacy Matters

SCAN ME!

Toni's Story

54% OF U.S. ADULTS READ BELOW A 6TH GRADE LEVEL 2024-2025 Literacy Statistics

What is Health Literacy?

"Ability to obtain, process, and understand basic health information in order to make appropriate health decisions."

Health Literacy in Healthy People 2030

Toni's Story: Health Literacy in Action

- Agreed to what she thought was a simple surgical "repair.
- Struggled with reading and didn't know what questions to ask.
- She said, *I signed everything because I knew nothing would happen if I didn't.*
- Later—at a routine appointment—she learned she had actually undergone a **hysterectomy**.

This is what happens when health literacy gaps collide with complex consent forms and rushed systems.

Toni Cordell Health Literacy: Unknown Hysterectomy

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*"Research participants may understand **as little as one-third** of standard consent documents, especially when literacy is a barrier." (Kripalani et al., 2008)*

Clinical Research in Low-Literacy Populations: Using Teach-Back to Assess Comprehension of Informed Consent and Privacy Information

Toni isn't an outlier - This Happens Every Day

What s Under The Surface

- Shame
- Cognitive overload
- Misinterpretation
- Fear of appearing incompetent
- Feeling intimidated or stressed
- The emotional burden of consent

Lived Experiences

- "I feared you would see my brain twisting like a rusty wheel trying to decode those ink lines."
- *"By the time I reached the end of a sentence, I had no clue what it meant.*
- *"I didn't know 'positive' could be bad.*
- *"Low literacy isn't lack of intelligence. It s lack of opportunity.*

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Signing a form is not the same as understanding it.

IF INFORMED CONSENT IS TRULY ROOTED IN PROTECTING PEOPLE, THE NEXT QUESTION IS:

How do we make sure people actually understand what they're consenting to?

...not just hearing the words, not just being handed the form, but genuinely comprehending it?

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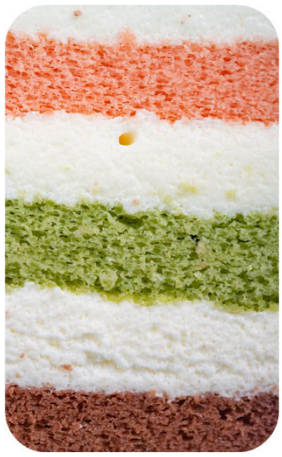
WHY YOU NEED LAYERED EXPLANATIONS

Educated participants struggle with research concepts.

Layered explanations help.
They break information into small chunks and reinforce it in different ways until understanding is reached.



How much layering?
It depends on the **complexity and risk** of the study
simple studies need fewer layers; complex or high-risk studies require more.

AHRQ Informed Consent and Authorization Toolkit for Minimal Risk Research

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HOW DO WE ENSURE COMPREHENSION?

TEACH BACK METHOD

WHAT IS IT?

A simple technique where you ask participants to explain study information **in their own words**.

A *"universal health-literacy precaution"* that verifies true understanding.

WHAT DOES IT DO?

- Creates open, two-way communication
- Uses participant-specific questions
- Identifies misunderstandings in real time
- Improves comprehension of study information
- Strengthens participant decision-making

Clinical Trials Informed Consent: An educational intervention to improve nurses' knowledge and communication skills

Use of Teach-Back During Informed Consent In Cancer Clinical Trials

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Teach Back Method: Cyclical Process

Part 1: Introduce Teach Back
"It's my job to explain things clearly. To make sure I did, can you tell me in your own words what you understand about this research study?"

Part 2: Checking Comprehension, Not Memory
"Tell me in your own words about the goal of this research and what will happen to you, if you agree to be in this study?"

Part 3: Correct any Misunderstanding
"Let's go over the purpose again, I think I may not have explained it clearly."

Implementing Teach Back During Oncology Clinical Trial Informed Consent

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TEACH BACK TIPS

SUBTLE WORD CHOICES CAN MAKE A BIG DIFFERENCE

Break Up the Content
Ask Questions Throughout

Not Great	Much Better
"Do you have any questions?"	*"What questions do you have about what we've just reviewed?"*
"I want to ask you questions to be sure you understood everything."	*"I'm going to ask you some questions to make sure I've explained everything."*
"I want to see if you understand what I told you."	*"I want to make sure that I've done a good job explaining, and to clarify anything that isn't clear."*

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"What is Clear To You, Is Not Clear To Me."

RISK–BENEFIT BALANCE

Associations with the Term "Risk vs. Benefit"

"No risk, no reward." "Better safe than sorry." "Heros and Self-Sacrifice." "Fate, Divine Will, Destiny."

Why it's complex:

- Participants often overestimate benefits ("therapeutic misconception").
- Risks can be abstract or unlikely, making them feel "not real."
- Framing effects heavily influenced interpretation.
- Probabilities require numeracy skills.

"We all speak differently."

Health Literacy in Clinical Research

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What a Layered Explanation of Risk and Benefit Looks Like

LAYER 1
Define the idea

Risks: "Risks are possible side effects or changes in your health that could happen during the study."

Benefits: *"Benefits are good things that might happen, but they are not guaranteed."*

LAYER 2
Add basic context

Risks: *"Side effects can be mild, moderate, or rare. Not everyone gets them, but they are still important to know about."*

Benefits: *You may or may not personally feel better. The main purpose of the study is to learn information that could help others in the future.*

LAYER 3
Give a simple example

Risks: *"For example, some people may get a headache or feel sick to their stomach. Others may not feel anything at all.*

Benefits: *"For example, some people may notice a small improvement, some may not feel different, and others may only have side effects."*

LAYER 4
Explain the numbers in an easy way

Risks: *"Here's a simple way to picture it: if 100 people were in the study, a few might have a side effect, and many might not. It depends on the person.*

Benefits: *"If 100 people joined the study, only a small number might get a personal benefit. Most people join to*

Risks: *"To make sure I explained that clearly, can you tell me in your own words what risks or side effects you understand could happen?"*

Benefits: *"Can you tell me what you understand about the possible benefits, including that you may or may not get any benefit yourself?"*

**Use Teach Back to Check Understanding at Each Layer (e.g., Part 2 & 3 of the cyclical process).*

Health Literacy in Clinical Research
National Assessment of Adult Literacy (NAAL)
Clinical Research in Low-Literacy Populations: Using Teach-Back to Assess Comprehension of Informed Consent and Privacy Information

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"What is Clear To You, Is Not Clear To Me."

RANDOMIZATION

Associations with the Term "Random"

Social Awkwardness "That was so random," Memes: Random funny "Llama in pajamas," A stranger "random person," Gaming "Random Encounter"...

Why it's complex:

- Contradicts the usual healthcare experience where patients choose their treatment.
- Involves probability and chance.
- Affects expectations, hope, and trust.

"We all speak differently."

Health Literacy in Clinical Research

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What a Layered Explanation of Randomization Looks Like

LAYER 1
Define the idea

Randomization means you are put into a study group by chance.

No one (not you, not the study team) gets to choose your group.

LAYER 2
Add basic context

This is done to make the groups as fair and similar as possible.

Why groups are similar, researchers can better understand whether the study treatment actually works."

LAYER 3
Give a simple example

"For example, it works a lot like flipping a coin, drawing a number, or picking a name from a hat.

Everyone has the same chance of being in each group.

LAYER 4
Explain the numbers in an easy way

"If there are two groups, it's like this:

If 100 people join the study, about 50 would be put in Group A and about 50 in Group B simply by chance."

(If your study has more than two groups, you can adjust this phrasing.)

"To make sure I explained that clearly, can you tell me in your own words how people are placed into study groups?

Can you explain what it means that the group you end up in is based on chance, not choice?"

**Use Teach Back to Check Understanding at Each Layer (e.g., Part 2 & 3 of the cyclical process).*

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"What is Clear To You, Is Not Clear To Me."

BLINDING

(SINGLE VS. DOUBLE)

Associations with the Term "Blind"

Assistive Device "braille", Physical Structures "window blinds" "blind spot," Computers "blind search," Music/Art "blind audition," playing cards "blind draw," Hunting "hunting blind"…

Why It's Complex:

- **Participants assume the study team always knows everything.**
- **Requires understanding objectivity and bias.**
- **Some cultures distrust "not knowing."**

"We all speak differently."

Health Literacy in Clinical Research

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What a Layered Explanation of Blinding Looks Like

Blinding means that some people in the study do not know which treatment or group they are in. This helps keep the study fair."

LAYER 1
Define the idea

LAYER 2
Add basic context

"Blinding is used so that people s expectations do not change how they feel or report their symptoms. It also helps the research team collect results without being influenced by what they hope will happen.

"For example, if you knew which treatment you were getting, you might expect it to work — and that could change how you feel or what you report. If the research team knew, they might also treat people differently without meaning to. Blinding prevents this."

LAYER 3
Give a simple example

LAYER 4
Explain the numbers in an easy way

"There are different levels of blinding:

- ***Single-blind: You don't know your group, but the study team does.***
- ***Double-blind: Neither you nor the study team knows your group.***
- ***Unblinded: Sometimes certain staff must know for safety reasons, but they will***

"To make sure I explained that clearly, can you tell me in your own words what blinding means in this study?

Can you explain why it's helpful that you (and sometimes the researchers) don't know which group you are in?"

****Use Teach Back to Check Understanding at Each Layer (e.g., Part 2 & 3 of the cyclical process).***

Health Literacy in Clinical Research
National Assessment of Adult Literacy (NAAL)
Clinical Research in Low-Literacy Populations: Using Teach-Back to Assess Comprehension of Informed Consent and Privacy Information

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Resources!

Tools to Assist

Tools

- Flesch-Kincaid Readability Tests
- Readable
- Hemingway Editor

Resources

- National Assessment of Adult Literacy (NAAL)
- Digital.gov
- Just Pain Clear
- Health Literacy in Clinical Research
- The AHRQ Informed Consent and Authorization Toolkit for Minimal Risk Research

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TEACH BACK

Takeaways

- *It's more than a knowledge check.*
- *It's a way of teaching the study to the participant.*
- *Use a conversational approach.*
- *Use teach-back during the entire consent process.*
  - *Ex: Divide consent into meaningful sections.*
- *Don't wait to ask questions until the end!*

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Now, Let's Dig Into The Details

with Stephanie Warth and Kimberly Luebbers

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Limited English Proficiency

Information must be presented in a language understandable to the participant. 45 CFR 46.116 & 21 CFR 50.20

What is Limited English Proficiency?

When English is not spoken as a primary language, impacting the ability to read, write, speak, or understand English.

Belmont Principle: Justice

Mandates the fair and equitable selection of research subjects, ensuring that the burdens and benefits of research are distributed justly.

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Limited English Proficiency

Applicable Federal Regulations: 45 CFR 46.117

(b)1 A written informed consent form that meets the requirements (in .116)…The investigator shall give either the subject/LAR **adequate opportunity to read the informed consent form** before it is signed; alternatively, this form may be **read to** the subject/LAR

(b)2 "A **short form written informed consent form** stating that the elements of informed consent [in .116]…have been **presented orally** to the subject /LAR, and that the key information required by §46.116(a)(5)(i) was presented first to the subject, before other information, if any, was provided. **The IRB shall approve a written summary of what is to be said to the subject/LAR**. When this method is used, there shall be a witness to the oral presentation.

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Limited English Proficiency

International Council for Harmonization Good Clinical Practice

Per ICH GCP 2.8.9

- **Impartial witness should be present during the entire informed consent discussion**
- **Participant still should sign for themselves if possible**

Witness should sign form as well, attesting that the written info was accurately presented and apparently understood

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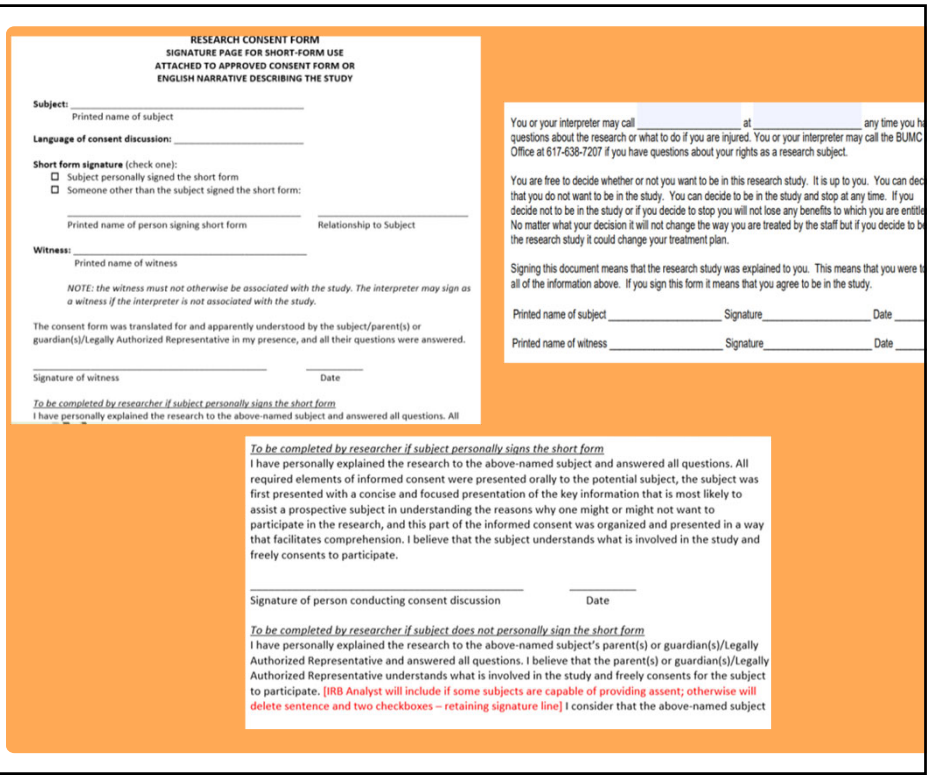
Informed Consent Short Form

The Not-So-Short Short Form



RESEARCH CONSENT FORM
SIGNATURE PAGE FOR SHORT-FORM USE
ATTACHED TO APPROVED CONSENT FORM OR
ENGLISH NARRATIVE DESCRIBING THE STUDY

Subject: _____
Printed name of subject

Language of consent discussion: _____

Short form signature (check one):
☐ Subject personally signed the short form
☐ Someone other than the subject signed the short form:

_____ _____
Printed name of person signing short form — Relationship to Subject

Witness: _____
Printed name of witness

NOTE: the witness must not otherwise be associated with the study. The interpreter may sign as a witness if the interpreter is not associated with the study.

The consent form was translated for and apparently understood by the subject/parent(s) or guardian(s)/Legally Authorized Representative in my presence, and all their questions were answered.

_____ _____
Signature of witness — Date

To be completed by researcher if subject personally signs the short form
I have personally explained the research to the above-named subject and answered all questions. All

You or your interpreter may call _____ at _____ any time you h
questions about the research or what to do if you are injured. You or your interpreter may call the BUMC
Office at 617-638-7207 if you have questions about your rights as a research subject.

You are free to decide whether or not you want to be in this research study. It is up to you. You can dec
that you do not want to be in the study. You can decide to be in the study and stop at any time. If you
decide not to be in the study or if you decide to stop you will not lose any benefits to which you are entitle
No matter what your decision it will not change the way you are treated by the staff but if you decide to b
the research study it could change your treatment plan.

Signing this document means that the research study was explained to you. This means that you were t
all of the information above. If you sign this form it means that you agree to be in the study.

Printed name of subject _____ Signature _____ Date _____

Printed name of witness _____ Signature _____ Date _____

To be completed by researcher if subject personally signs the short form
I have personally explained the research to the above-named subject and answered all questions. All required elements of informed consent were presented orally to the potential subject, the subject was first presented with a concise and focused presentation of the key information that is most likely to assist a prospective subject in understanding the reasons why one might or might not want to participate in the research, and this part of the informed consent was organized and presented in a way that facilitates comprehension. I believe that the subject understands what is involved in the study and freely consents to participate.

_____ _____
Signature of person conducting consent discussion — Date

To be completed by researcher if subject does not personally sign the short form
I have personally explained the research to the above-named subject's parent(s) or guardian(s)/Legally Authorized Representative and answered all questions. I believe that the parent(s) or guardian(s)/Legally Authorized Representative understands what is involved in the study and freely consents for the subject to participate. [IRB Analyst will include if some subjects are capable of providing assent; otherwise will delete sentence and two checkboxes – retaining signature line] I consider that the above-named subject

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COMPLEX

Policies Differ Between Institutions

Who can be a witness?
- Family member, study staff, translator, or someone else

Who can be an interpreter?
- Family member, study staff, or certified professional

Does exempt research carry loosened requirements?

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Scenario

Details:

1. **Spanish speaking patient in clinic seems like a good candidate for your study**
   - **Prospective, Randomized, Placebo Controlled Trial of GLOW DRUG for Pain Relief after Surgical Staple Removal**
2. **Your PI approaches them about the study and they are interested**

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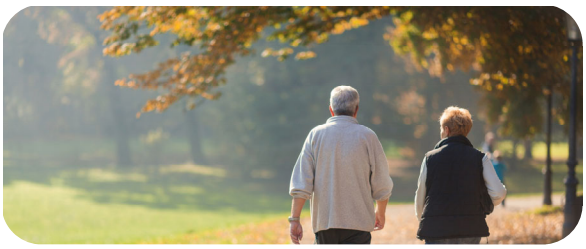
Life Limiting Illness



What is a Life Limiting Illness?

A life limiting illness is an incurable, progressive condition that will shorten a person's life with death often the expected result.

Increased Potential for Undue Influence

Undue influence occurs when inappropriate persuasion or excessive incentives is used to overpower someone's judgement.

- **Imperative to discuss the difference between research and standard of care**

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Other Considerations

Life Limiting Illness

Complex Protocols

Often there are **genetic components** or **novel treatment** methods.

- It is important to break down these complex concepts into simple ideas

Support System Dynamics

Typically, these patients attend medical appointments with family or other support.

Managing Expectations

It is important to clearly define the purpose of research and the study.

- Research is not treatment
- Effectiveness of intervention may not be study aim

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Scenario

Study Details:

1. **Open label, Randomized Controlled, Phase 3 trial comparing Selpercatinib to SOC therapy**
2. **Participants with stage 4 lung cancer**
3. **For tumors with evidence of the RET gene mutation**
4. **Participants must have progressed following most recent line of therapy**
5. **Must be randomized within 10 weeks of last dose of therapy**
6. **Life expectancy greater than 6 months**

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Additional Protections for Children

45 CFR 46 Subpart D - Additional Protections for Children Involved as Subjects in Research

Definitions:

a) Children are persons who have not attained the legal age for consent to treatments or procedures involved in the research in the state where research will be conducted.

b) Assent means affirmative agreement to participate in research

c) Permission means the agreement of parent(s) or guardian(s) to the participate

d) Parent means a child's biological or adoptive parent.

e) Guardian means an individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care.

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Summary Table on Subpart D, 45 CFR 46 and 21 CFR 50:Additional DHHS Protections for Children Involved as Subjects in Research; Additional Safeguards for Children in Clinical Investigations (FDA)

Permissible Research with Children

45 CFR 46 (OHRP), 21 CFR 50 (FDA)	Category	Requirements The IRB must determine the following before children may be involved as subjects:	Parental Permission
46.404, 50.51	Research not involving greater than minimal risk[1]	Adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians, as set forth in 46.408 and 50.55	Permission from one parent may be sufficient
46.405, 50.52	Research involving greater than minimal risk[1] but presenting the prospect of direct benefit[2] to the individual subjects	a) The risk is justified by the anticipated benefit to the subjects; b) The relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches; and c) Adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians, as set forth in 46.408 and 50.55	Permission from one parent may be sufficient
46.406, 50.53	Research involving greater than minimal risk[1] and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition	a) The risk represents a minor increase over minimal risk; b) The intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social or educational situations; c) The intervention or procedure is likely to yield generalizable knowledge about the subjects' disorder or condition which is of vital importance for the understanding or amelioration of the subjects' disorder or condition; and d) Adequate provisions are made for soliciting assent of the children and permission of their parents or guardians, as set forth in 46.408 and 50.55.	Permission must be obtained from both Parents

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Summary Table on Subpart D, 45 CFR 46 and 21 CFR 50: Continued

Permissible Research with Children			
46.407, 50.54	Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of Children	a) The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children; and b) The Secretary of DHHS or Commissioner of Food and Drugs for the FDA, after consultation with a panel of experts in pertinent disciplines (for example: science, medicine, education, ethics, law) and following opportunity for public review and comment, has determined either: 1. That the research in fact satisfies the conditions of 46.404 and 50.51, 46.405 and 50.52, or 46.406 and 50.53, as applicable, OR 2. The following: i. The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health and welfare of children; ii. The research will be conducted in accordance with sound ethical principles; iii. Adequate provisions are made for soliciting the assent of children and the permission of their parents or guardians, as set forth in 46.408 and 50.55.	**Permission must be obtained from both Parents**

1. "Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests," 45 CFR 46.102
2. "The prospect of direct benefit" means the intervention or procedure holds out the possibility of direct benefit to the individual subject, or the study involves a monitoring and diagnostic procedures that may contribute to the subject's care or well-being." 45 CFR 46.405, 21 CFR 50.52

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Summary Table on Subpart D, 45 CFR 46 and 21 CFR 50:Additional DHHS Protections for Children Involved as Subjects in Research; Additional Safeguards for Children in Clinical Investigations (FDA)

Requirements for Assent of Children		
45 CFR 46 (OHRP), 21 CFR 50 (FDA)	**Category**	**Requirements** **The IRB must determine the following before children may be involved as subjects:**
46.408, 50.55	Requirements for assent by children	• The IRB must determine that adequate provisions are made for soliciting the assent of the children when in the judgment of the IRB the children are capable of assenting. • In determining whether children are capable of providing assent, the IRB must take into account the ages, maturity, and psychological state of the children involved. This judgment may be made for all children to be involved in research or clinical investigations under a particular protocol or for each child, as the IRB deems appropriate.
	Documentation of assent	• When the IRB determines that assent is required, it shall also determine whether and how assent must be documented.

	Waiver of assent	• The assent of the children is not a necessary condition for proceeding with the clinical investigation if the IRB determines:
		  • that the capability of some or all of the children is so limited that they cannot reasonably be consulted, or
		  • that the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research.
		• Even where the IRB determines that the subjects are capable of assenting, the IRB may still waive the assent requirement for minimal risk research in which consent may be waived under 46.116, or in which assent may be waived under 50.55. See IRB Guidance on waiving consent and waiving documentation of consent.

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Scenario

Zoom Poll Question

Case Scenario: Blood Biomarker Study in Children with Mild Asthma

Title:
Inflammatory Biomarkers in Children With Mild Persistent Asthma

Purpose:
To measure levels of specific inflammatory biomarkers in children with mild persistent asthma and compare them to children without asthma.

Participants:
- 80 children total (40 children w/mild persistent asthma & 40 healthy controls)
- Ages12-17 years old
- Recruited from a pediatric outpatient clinic

Study Procedures:
- Medical Record Review
- Single Blood Draw
- Symptom Questionnaire

Benefits:
- No direct benefit to participants
- May contribute to improved understanding of pediatric asthma

What regulatory risk category would apply to this scenario?

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Scenario

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Additional Protections for Children

Thing we need to consider for children:

Parental Permission:
Because minors generally cannot legally provide full informed consent, researchers must obtain permission from a parent or legal guardian.

Child Assent:
Even though parents give permission, children who are capable must provide assent.

Factors to consider:
- Age and developmental level
- Cognitive ability
- Emotional maturity
- Health status

Summary
When consenting children for research (such as a short asthma survey), investigators must ensure:
- Proper parental permission
- Meaningful child assent
- Minimal risk
- Clear explanation of voluntariness
- Strong confidentiality protections
- Safeguards against coercion

The central ethical principle is respect for developing autonomy while providing appropriate protections for vulnerability.

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Additional Protections for Children

Other considerations:

Dissent
A child's **dissent** (i.e., their actual objection to research) should be considered binding in non-therapeutic research.

Assent of a child is not a necessary condition for proceeding with the research if the IRB finds that the capability of some or all of the children is so limited that they cannot be reasonably consulted or that the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research.

Permission of the parents or legally authorized representative is still a federal requirement.
Only the parent(s) may grant permission for the child's participation in research.
Assent is to be sought from the child, only after permission has been obtained from one or both of the parents.
Grandparents and other relatives or caregivers may not grant permission unless they have been granted formal custody of the child by a court.

Children in State Custody (Wards of State)
According to the Department of Children and Families (DCF) applicable policies and by virtue of the court order granting DCF legal custody of certain children (e.g., foster children), that Department is the agency that is authorized to grant permission for participation in research for children in their custody.
Decisions to grant permission for research is made on a case-by-case basis by DCF and consent is provided by an appropriate representative of DCF.
If a child has begun research procedures with the consent of a parent but is subsequently placed in the custody of DCF while undergoing research interventions, consent must be sought again from the appointed advocate for the child at DCF in order to continue participation in the research.

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Additional Protections for Children

Emancipated Minor

According to Vermont Statute, an **emancipated minor** means a minor who:

a) has entered into a valid marriage, whether or not such marriage was terminated by dissolution;
b) is on active duty with any of the armed forces of the United States of America; or
c) has been, by a court of law, ordered emancipated.

- To become an "emancipated minor" the minor must petition the probate court. There are multiple stipulations that must be met by the minor, and the court must find that emancipation would be in the best interest of the minor.
- If the stipulations are met, the court will issue an order of emancipation.
- In certain limited circumstances, it may be appropriate to allow an emancipated minor to consent to participate in a research study in the absence of the permission of a parent or legal guardian if the minor has the sufficient capacity to consent to the procedures involved in the research study. Each situation is judged on a case-by-case basis.

My advice here is in these very unique situations – consult with your IRB.

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Surrogate Consent for Research

45 CFR 46.102(c) and 21 CFR 50.3(1) Surrogate Consent for Research (Legally Authorized Representatives)

A legally authorized representative (LAR) is defined in both HHS and FDA regulations as an individual or judicial or other body authorized under applicable law to consent on behalf of a potential participant to participate in the procedure(s) involved in the research.

IRB Approval
IRB must approve enrollment of vulnerable populations and special protections may be needed for cognitively impaired/limited decision/making capacity participants.

Cognitively Impaired and/or Limited Decision-making Capacity
- Unconscious/experiencing profound impairment of consciousness
- Incapable of making an informed decision due to other reasons

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Surrogate Consent for Research

Use of Legally Authorized Representative (LAR)

Legally Authorized Representative (LAR) consent is used in research when subjects lack decision-making capacity due to conditions like dementia or acute trauma.

We need to:
- Follow state laws,
- IRB approval to use LAR consent,
- Verify and document incapacity,
- Obtaining signature on the Informed Consent Form (ICF),
- Re-consenting the participant if they regain capacity.

Key principles include minimizing coercion and ensuring the LAR understands the study.

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Surrogate Consent for Research

Assessment of Capacity

For a legally authorized representative (LAR) to give informed consent for a prospective adult human subject to take part in human research, the prospective human subject must be found to be incapable of making an informed decision as defined in § 18 V.S.A. § 9701.

This means that the prospective adult subject is unable to understand the nature, extent or probable consequences of the proposed research or is unable to make a rational evaluation of the risks and benefits of alternatives to the proposed research.

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Surrogate Consent for Research

Assessment of Capacity

You need a plan to assess capacity and solicit consent for continued participation for adult subjects who will or may regain decision making capacity.

The plan needs to describe who will be assessed for consent, under what conditions, and how the assessment will be performed. There needs to be a written plan about how capacity for consent will be documented.

The IRB along with the research team will review and assess the following:

- Study risk
- Anticipated benefits
- Complexity of the study
- Availability of Legally Authorized Representative(s)
- Patient characteristics
- Determination of additional safeguards

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Surrogate Consent for Research

Reconsent: Decisional Capacity Changes

Regained Capacity

- If a subject regains adequate decision-making capacity, they should be asked to complete the consent process and agree to continued participant .
- If at any time, the subject indicates that they do not want to continue study participation, they should be withdrawn from study.

Decreased Capacity

For subjects who develop decisional impairment after agreeing to participate, the LAR becomes responsible for making medical decisions:

- Study protocol should include a plan for LAR permission for study populations who are likely to experience decreased decisional capacity.
- LAR should be informed about the study, formal written consent from the LAR is not required because consent was initially obtained from subject.
- LAR has the authority to withdraw the subject if they conclude that it is in the subject's best interest.

Consent form should include a statement that informs the subject about this matter and encourages them to discuss the study with their LAR

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Scenario

Which of the following are scenarios could potentially use LAR (Legally Authorized Representative) when a potential participant cannot provide informed consent themselves?

1. Research Involving Children (Minors)
2. Adults with Cognitive Impairment
3. Unconscious or Critically Ill Patients
4. Individuals with Severe Mental Illness
5. Intellectually Disabled Adults
6. Research in Emergency Settings (Exception from Informed Consent – EFIC)

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Scenario

Zoom Poll Question

Case Scenario: Stroke Patient in a Clinical Trial

Our hospital is conducting a clinical trial to test a new medication aimed at reducing brain damage after an acute ischemic stroke.

Mr. Thomas, a 72-year-old man, is brought to the emergency department with sudden weakness and loss of speech. Imaging confirms a severe stroke. He is conscious but:

- Unable to speak
- Unable to understand complex information
- Disoriented and confused

The research team determines that Mr. Thomas **does not have the capacity to provide informed consent** because he cannot:

- Understand the nature and purpose of the study
- Appreciate the risks and benefits
- Communicate a clear decision

Since the medication must be administered within a short therapeutic window, waiting for recovery of capacity is not possible.

Why is the use of an LAR needed/ appropriate in this scenario?

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Informed Consent

Takeaways – Being a Participant Advocate

Advocacy

- Begins with being aware and informed about the rules, regulations, policies and procedures related to consent as well as being knowledgeable about the different pathways to consent.
- Includes planning appropriate consent procedures, following rules, regulations, policies and procedures.
- Ensuring that our participants are given all the necessary information, in an appropriate way, to make an informed decision about participation. Which includes ensuring we have appropriate resources available and prepared to provide that information.

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RESOURCES

What Not To Do // Informed Consent Training
45 CFR 46
FDA 21 CFR 50.25
Henry Beecher's Contributions to the Ethics of Clinical Research
Ethical Issues in Patient Data Ownership
Human Factors in Electronic Health Records Cybersecurity Breach: An Exploratory Analysis
Pitfalls and Challenges of Consenting to Genetic Research Studies
Corporations, high-stakes biomedical research, and research misconduct: yes they can (and sometimes do)
Ethical issues in the use of genetic predictions of aggressive behavior in the criminal justice system: a systematic review
Health Literacy in Clinical Research
National Assessment of Adult Literacy (NAAL)
2024-2025 Literacy Statistics
Health Literacy in Healthy People 2030
Toni Cordell Health Literacy: Unknown Hysterectomy
Clinical Research in Low-Literacy Populations: Using Teach-Back to Assess Comprehension of Informed Consent and Privacy Information
The AHRQ Informed Consent and Authorization Toolkit for Minimal Risk Research
Use of Teach-Back During Informed Consent in Cancer Clinical Trials
Clinical Trials Informed Consent: An educational intervention to improve nurses' knowledge and communication skills
Implementing Teach Back During Oncology Clinical Trial Informed Consent
Plain Language Guide Series
Just Plain Clear Glossary
Clinical Research Glossary
Flesch Kincaid Calculator
Readable
Hemingway Editor

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Additional Resources by Organization

BU/BMC:

HRPP Policies | Office of Human Research Affairs

Seminar Library | Clinical Research Resources Office

10/9/24 - **Tools in the Consent Backpack: Unpacking how to include participants with limited English proficiency**

MUSC:

IRB Forms & Guidance | MUSC Research

UF:

Obtaining Consent: Special Situations » Institutional Review Board » University of Florida

UVM:

IRB Policies and Procedures | Research Protections Office (RPO) | The University of Vermont

Obtaining and Documenting Written Informed Consent for Research

WVU:

Toolkit Library | Office of Human Research Protections | HRP 090 SOP Informed Consent Process for Research

WVCTSI CT COE SOP COE-11001 ICF Development and Implementation_10sep2025.pdf

WVCTSI CT COE Informed Consent Process Resource

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THANK YOU

RESEARCH PROFESSIONALS NETWORK

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