

Beyond Documentation: Best Practices for Consent

Speaker:

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“The single biggest problem in communication is the illusion that it has taken place.”

~ George Bernard Shaw

Goals

- When do you use the different templates?
- Discussion for Best Practices

The BEST Best Practice

Put yourself (or your kid,
or your mom, or your
husband) in their shoes

BASICS

What's On Our Forms Page?

Main consent template (with and without HIPAA language)

- Update if you can, but not required for older studies.
- Use this for all Expedited and Full Board protocols unless a Sponsor template is **mandated**.

What's On Our Forms Page?

- The Board requires our template used unless your Sponsor requires theirs.
 - Easier to review
 - Ensures old language isn't used
 - Ensures most recent regulatory requirements are present

What's On Our Forms Page?

Sample Information Sheet for Exempt research

- Remove HIPAA language if not applicable
- Modify to suit your needs:
 - Email
 - Phone script
 - letter

What's On Our Forms Page?

Assent form

- Use for ages 7-13

What's On Our Forms Page?

Short form

- Use for when the consent is not translated into the participant's language.
- Must be approved for use by the IRB

What's On Our Forms Page?

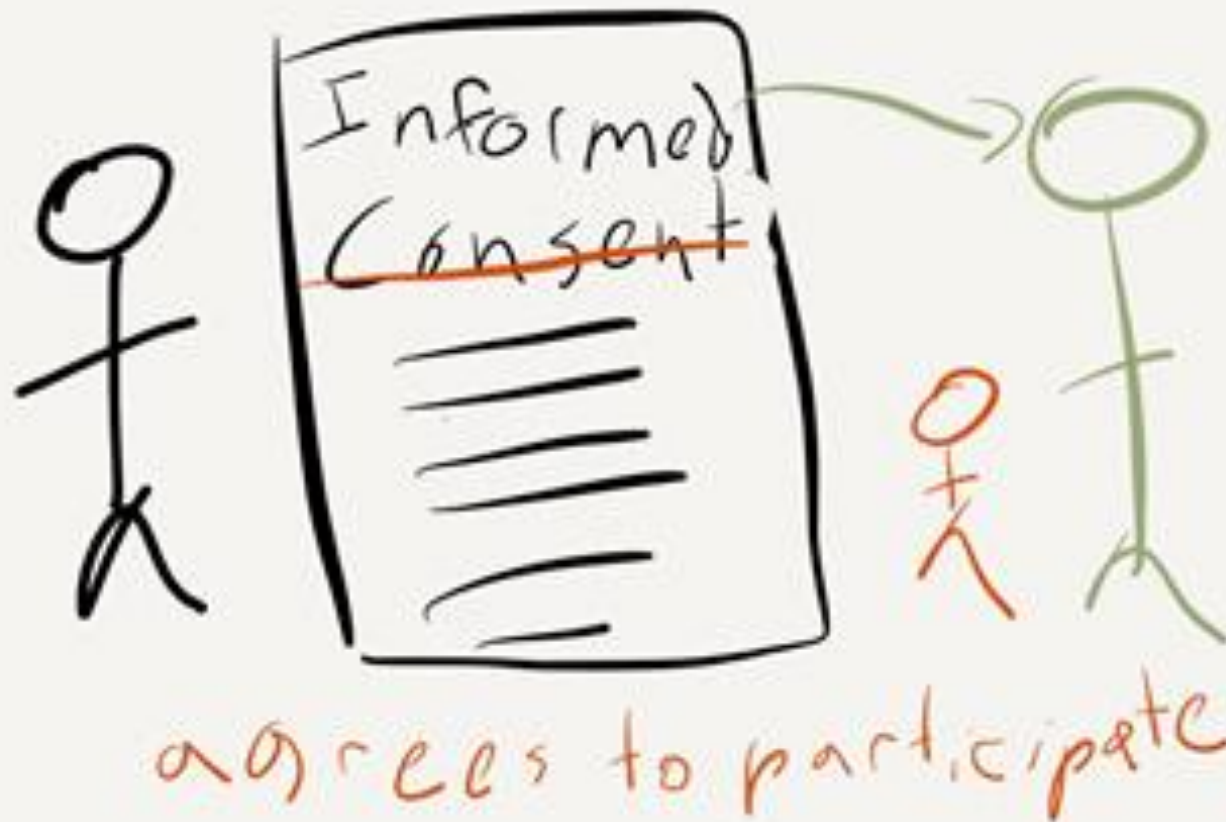
Boilerplate Consent form Language

- When a Sponsor *does* mandate the use of their form, this must be used to ensure local language



So Let's Dig In!!!

Remember –
It's *Informed* Consent – not
just Consent



Why is this important?

A truly informed patient....

- has stronger protocol adherence
- is less likely to drop out
- becomes an advocate for clinical research

Regulations

It's the right thing to do

Practical Planning

- Plan on what you'll call things and be consistent
 - Group interview or Focus Group?
 - Baseline visit or Visit 1?
 - Control or Healthy Control?
- Use lay language (more later)
- Process checklists

Practical Planning

- Tools, Aids
 - Flip charts
 - Break down more complicated procedures into pictures
 - Calendar of Events
 - Videos
 - Flow charts

Examples

Video of an MRI

Truly lay language of Whole Genome Sequencing

Picture of stereotaxic equipment in use

Flip chart of 6-minute walk test, grip strength

If most of your research involves some common activities, invest in this

Practical Planning

- Who will actually do it?
 - Good communicator?
 - Not someone in authority (doctor, teacher, etc.)
 - Put your best person in that spot.

Consent is a Process

- Begins with the first contact (flyer, phone call, advertisement)
- Is ongoing through the research
- Continues beyond study termination

A decorative graphic in the top-left corner consisting of a cluster of overlapping hexagons in various shades of green.

But what does that
actually look like?

First Contact



First Contact

- Give them some details, but not too much – don't overwhelm
- **Plan** on what you'll tell them when they call in or when you first approach
- Use every opportunity to inform (scheduling call, follow up reminders, etc.)

Balance the act of *recruitment* vs. *informed consent*

Manage Expectations from the Start

- Don't oversell benefits
- Don't use words like "its just...", "a few minutes....", "minimal risk", "discomfort" to downplay what may be real risks and discomforts
- Have you ever completed 16 questionnaires in one sitting?

Consider the Motivation of your Participants

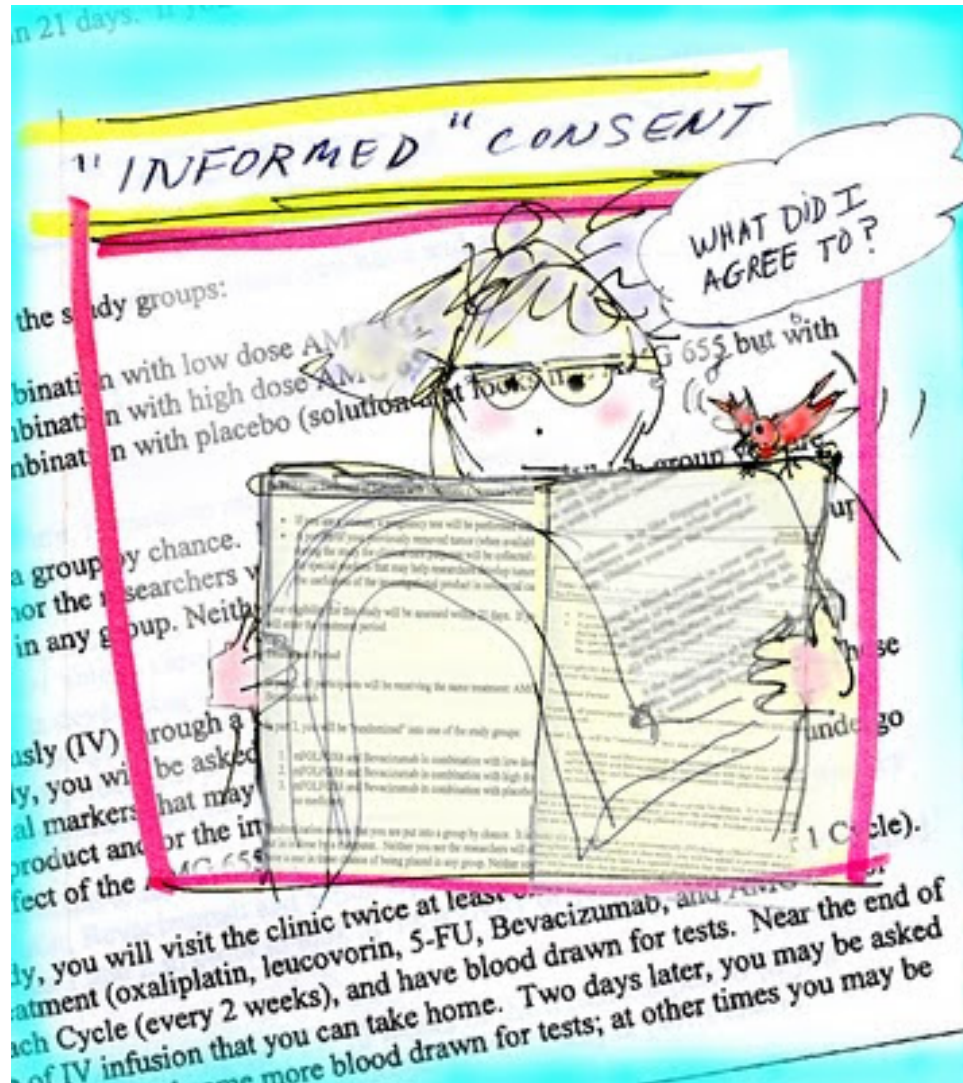
- The sicker that patient, the more you have to explain
- The higher the risk, the more you have to be clear
- The more money you are offering, the more you have manage

Consider Your Participant in General

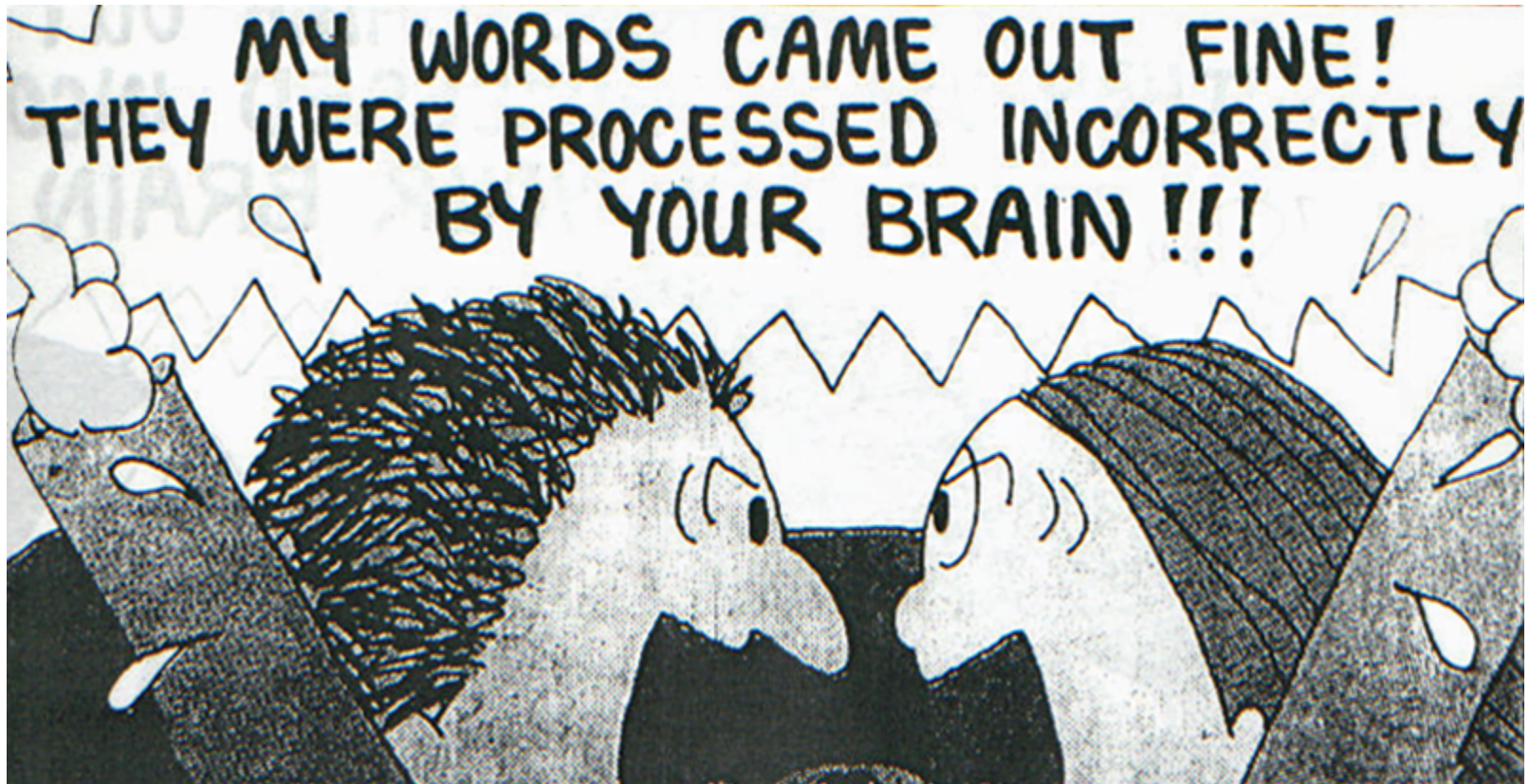
- Child?
- Desperate parent?
- Older?
- Not from this country?
- From a group that has been historically abused in research?
- From a group that is significantly different than you?
- Lots to lose? Lots to gain?



Documentation (AKA the consent form)



Lay Language, Lay Language, Lay Language



Ask an 8th Grader

- Adverse reactions (aka “side effects”)
- Biomarker (aka “part of your blood that helps us see how your body responds to the treatment”)
- Acute (aka “sudden”)
- Infusion (aka “a slow injection of the drug into your through a needle in your arm”)
- Congenital (aka “your child’s condition was present when she was born”)
- Subcutaneous (aka “under the skin”)

You will be in the study 3 weeks, which will involve 5 study visits. You will have 6 blood draws, 2 MRIs, and 5 urine collections, and we will conduct neurological testing twice as well as perform 3 MRIs

Vs.

You will be in the study 3 weeks, which will involve 5 study visits

Baseline Visit:

- Blood draw:.....
- MRI:.....
- Neuro Testing:.....

Visit 1 (3 days after baseline visit):

Size (and format) Matters

- Which one would you want to get and read?

CONSENT FORM

Title of Research: Bonorum Voluptua Eum Induo Alii Tincidunt

UAB IRB Protocol #: IRB-300000xx

Principal Investigator: Case Corpora M.D., Ph.D.

Sponsor: National Institute on Aging

Purpose of the Research

Lorem ipsum dolor sit amet, ad nulla facilis antiopam sed. Dicant graece ne sit, detracto recusabo vituperatoribus mel ne, omnes scripta referrentur cum an. Stet veritus lobortis cum in, ius alia saperet ut. Ad eum purto oratio adipisci, duo denique pericula ex.

Explanation of Procedures

BASELINE VISIT:

If you decide to be in the study, we would be following you for up to 24 months. While you are in the hospital, we would

- Ea vis putant bonorum percipitur, ne mutat maiorum has.
 - Quod elitr eirmod at ius
 - Pro ut graeco insolens sadipscung, pri ea delicata assueverit,
- impedit deterruissetEa vis putant bonorum percipitur, ne mutat maiorum has.
- Stet veritus lobortis cum in, ius alia saperet ut.
- Soluta assentior te nec, ex vim nibh appetere accommodareAfter you leave the hospital, we would

VISIT 2 (Lamenti visit):

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- An graeco eripuit explicari eam, vel autem reprehendunt etGive you some tests that measure attention and memory. This will take about 30 minutes.
- Give you some tests that measure how well you do on everyday activities.
- An graeco vel autem eripuit explicari eam, vel autem reprehendunt et impedit accusamus forensibus

Ad mel antiopam partiendo voluptatibus, quo clita essent accommodare no. Sale dicta ad vis, no usu veri deleniti legendos, qui ea amet munere conclusionemque. Ex per falli dicant detraxi

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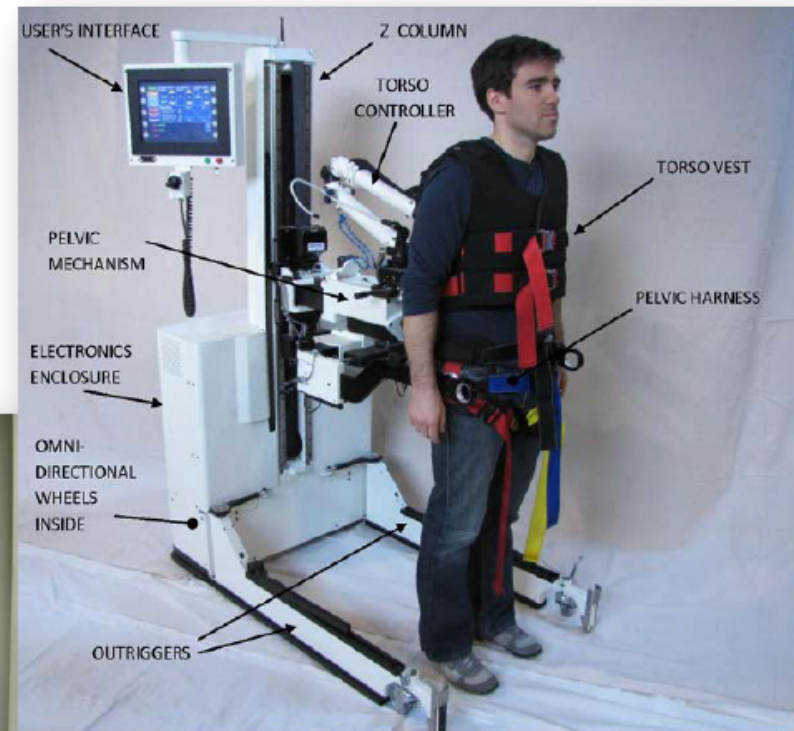
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Risks and Discomforts

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A Picture is Worth a 1000 Words

“Both forms of training will make use of body weight support provided by the KineAssist® device. The KineAssist is a robotic device that allows full freedom of motion for the body and pelvis during walking and balance tasks, and also helps to control your posture to enhance your balance and stability. The KineAssist also offers you safety while training and will catch you if you lose your balance. This assistance is available while you are strapped into the device with a harness and the device allows you to walk over the treadmill with minimal things affecting your walking.”



Courtesy of David A. Brown, PT, PhD

Organization of the Consent: Overall

- 11 pt font or higher
- 1" margins
- Use of white space
- Avoid repetition/redundancy
- Read aloud – see how it sounds
- Organize chronologically

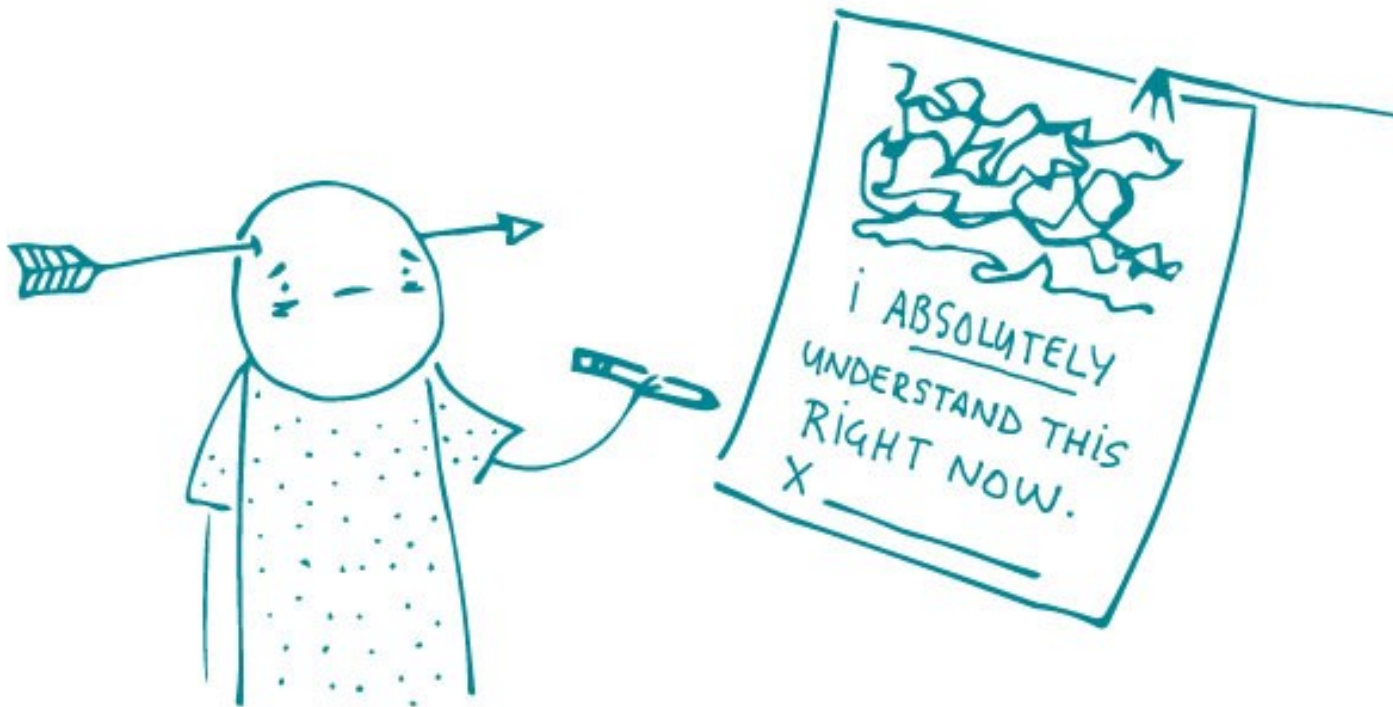
Why Grammar Matters

- Instills trust
- Aides comprehension

Comprehension

- Consider a comprehension check
- Do they really get it?

Ongoing



Beyond “Significant New Findings”

- Use every check-in to inform
- Consider how long apart interactions are
- How likely would your mother be able to put her hands on a consent form she signed a year ago?
- Why are they coming for *this* visit?
- Thank you notes
- And yes, significant new findings

