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Informed Consent in Research

North Carolina Translational and
Clinical Sciences (NC TraCS) Institute

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A Scenario…

You are conducting an informed consent discussion with a potential subject. The study involves the treatment of Amyotrophic Lateral Sclerosis with a new drug, injectable Sectroimab. Risks of the drug include transient ischemic attack and Raynaud's disease. You explain this to the subject during the discussion, and hope that the subject understands.

A Scenario…

What is Informed Consent?

What Elements Should be Included in Informed Consent?

How Do I Conduct Informed Consent Discussions?

Mock Consenting Session

Scenarios

What is Informed Consent?

The Purpose of Informed Consent…

…is for subjects to understand their role as a "subject of research".

…is to explain the purpose of research to the potential subject, including what their role would be and how the trial will work.

Why Do We Complete the Informed Consent Process?

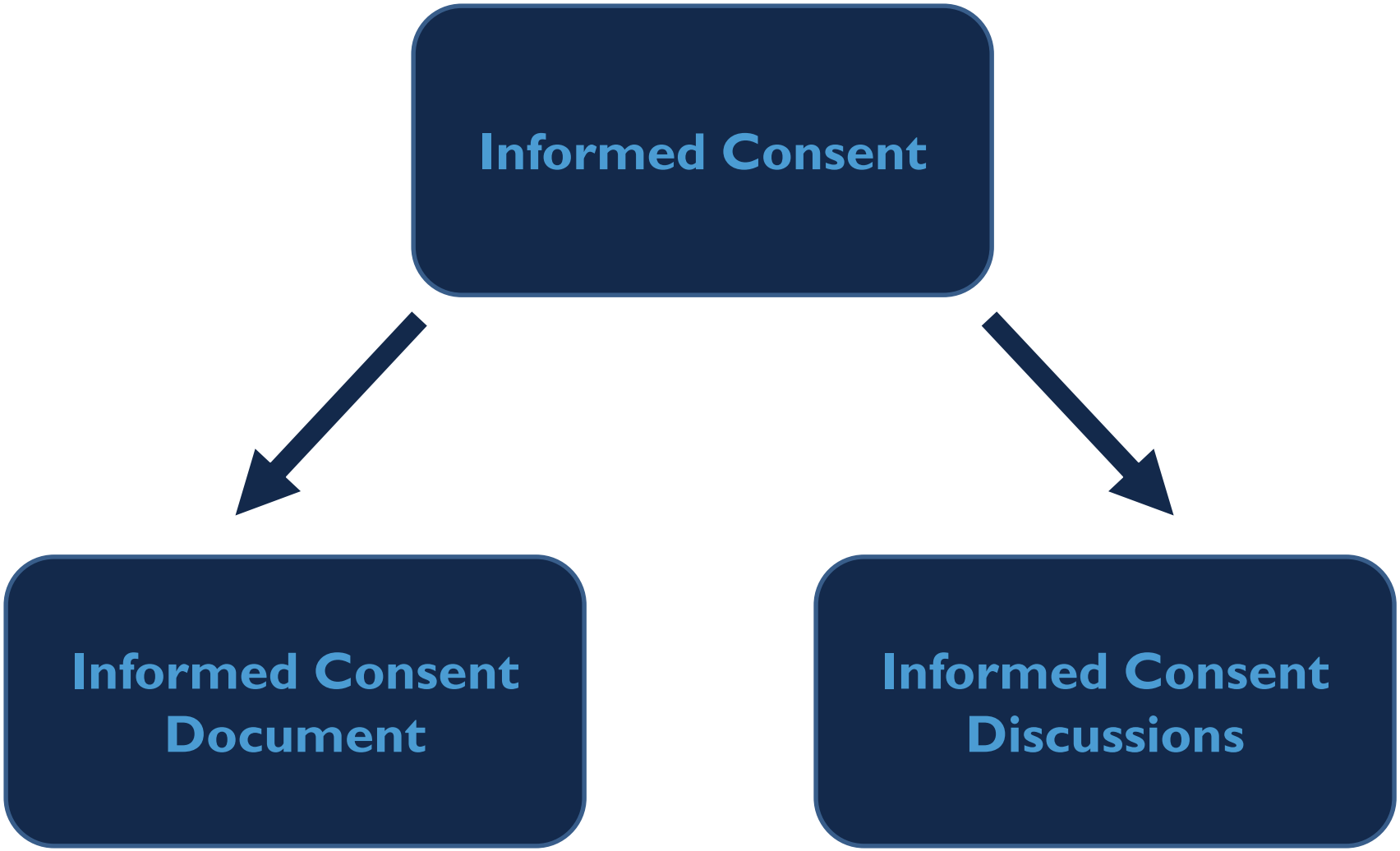
Belmont Report:

Consists of the three basic ethical principles that underlie acceptable conduct in human research- respect for persons, justice, and beneficence.

Nuremberg Code:

One of the ten main points in this code is the requirement for informed consent of participants.

"The voluntary consent of the human subject is absolutely essential"


Informed Consent
Informed Consent Document
Informed Consent Discussions

Informed Consent Document:

What Elements Should be Included?

Understandable to a person who is educated at an 8th grade level

Written in a language that the subject or representative understands

May not include any language where subject waives or appears to waive legal rights

May not include any language that releases any study team from liability or negligence

- The study involves research, that expected duration of participation, description of procedures, and identification of experimental procedures, and alternative procedures
- Study team contact information
- Statement that participation is voluntary, the refusal to participate involves no loss of benefits and that the subject can discontinue at any time
- Statement describing the extent of confidentiality for records and that the FDA or other applicable agencies may inspect those records
- Description of benefits to the subject or others
- Description of foreseeable risks or discomforts
- If greater than minimal risk, a statement as to if any compensation and/or medical treatment is available if injury occurs

If Applicable…

- Approximate number of subjects
- Statement that subjects will be informed about new information
- Additional costs that may result from participation
- That the research may involve risks to an embryo or fetus
- Circumstances in which the investigator will end the subject's participation
- If the subject withdraws, the procedures that will be followed
- Clinicaltrials.gov statement
- Certificate of Confidentiality Statement

What about HIPAA?

HIPPA's purpose is to establish standards to protect individual's protected health information (PHI), by…

Requiring appropriate safeguards to protect PHI

Setting limits and conditions on how we can use information without patient permission

Giving patients the ability to get a copy of their medical record, and request changes if applicable.

Informed Consent Discussion:

Ensuring Subject Understanding

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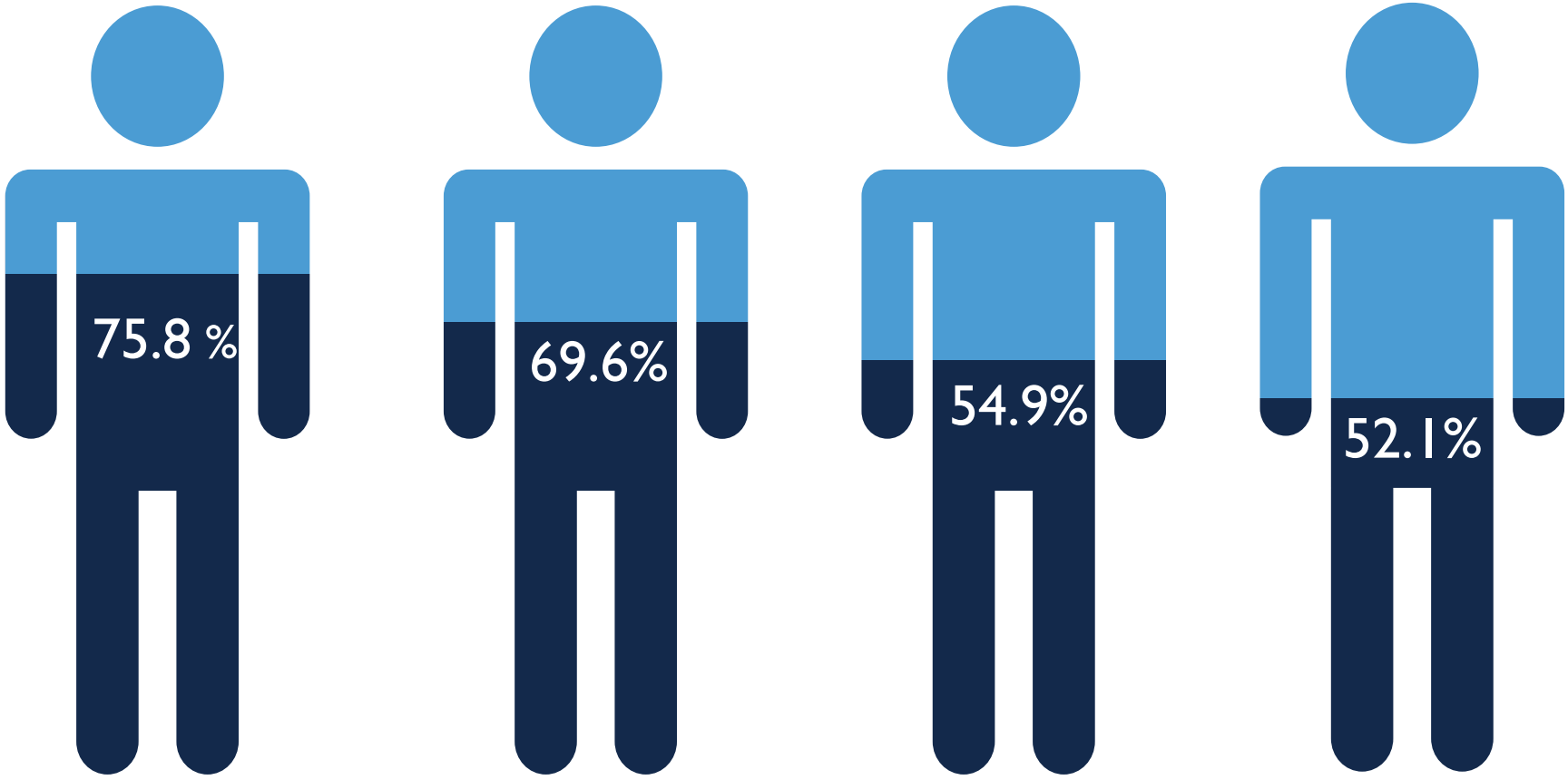
Remember the Scenario from Earlier?

- What was the drug?
- What was a risk?



Participants' understanding of informed consent in clinical trials over three decades: systematic review and meta-analysis. Tam, 2014

What is the Solution?

The 7 Questions:

1. Who?
2. Who (Part 2)?
3. What?
4. When?
5. Where?
6. Why?
7. How?

After Signing Consent…

Retain the original and…

Give the Subject a Copy of the Consent

Put a Copy of the Consent in the Medical Record (if applicable)

Don't Forget the Informed Consent Process Documentation!

This document is a record of the informed consent process. It states that best practices were followed during the informed consent discussion.

Questions?

Mock Consenting Session

Break into groups of three:

- **"Participant"**
- **"Consenter"**
- **"Observer"**

Rotate roles after you finish each consenting process

What would you do if…?

A Patient Says No?

- Thank them for their time!
- Collect the consent form from them.
- Do not seem upset or disappointed.
- Do not try to convince them otherwise. If they say no, end the consenting process there.

A Patient Seems "On the Fence"?

- Remind them that research is voluntary.
- Assure them that they can withdraw if they'd like, at any time.
- Do not coerce or try to "sell" the study to the potential participant.

A Patient's Companion is Answering for Them?

- Be respectful to the companion, but try to change the conversation to be about the potential participant.
- Make sure the patient verbally says "yes" before continuing.

A Clinic Staff Member Needs to See the Patient?

- Let the clinic staff member see the patient as soon as they ask.
- Follow-up with the clinic staff member prior to leaving the room regarding when you can come back.
- You cannot do any study related-procedures or collect data until the consent is signed.

A Patient Agrees but You Don't Believe They Comprehend?

- Ask questions about the study to gauge understanding
- If they cannot answer your questions appropriately, then you can politely say that "the study isn't the right fit for you right now", "let's talk about this another time", etc.

Thank you!

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