Informed Consent in Research

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A Scenario...

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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...

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What is Informed Consent?

What Elements Should be Included in Informed Consent?

How Do I Conduct Informed Consent Discussions?

Scenarios

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What is Informed Consent?

What is Informed Consent?

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...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.

The Purpose of Informed Consent...

What is Informed Consent?

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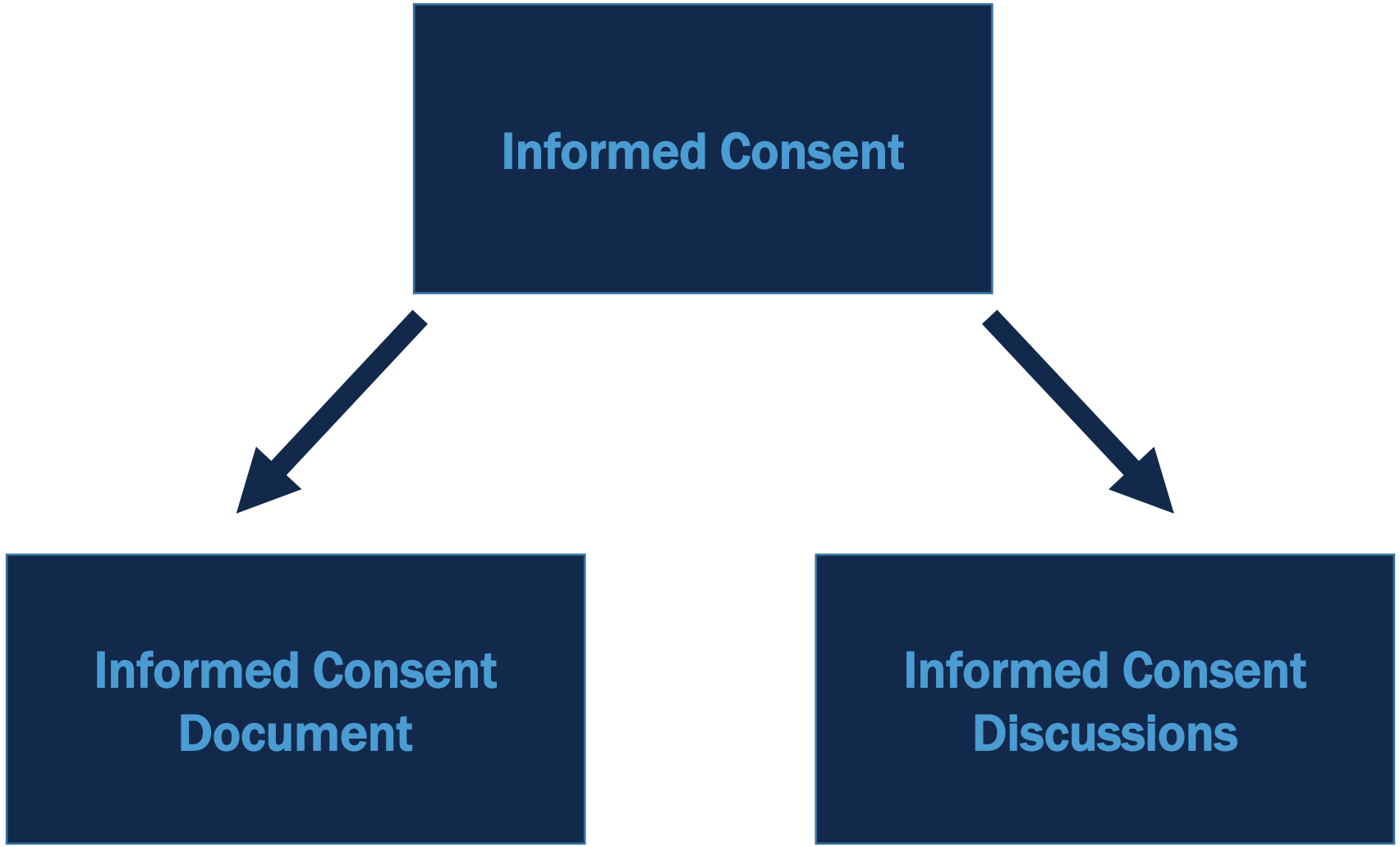

Why Do We Complete the Informed Consent Process?

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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"

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Informed Consent Document

What Elements Should be Included?

Informed Consent Document

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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

New Common Rule: Concise Summary

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"Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research."

What is Included in an Informed Consent?

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8 Elements are Required Per 45 CFR 46.116(b):

That the Study Involves Research, and an Explanation of that Research

Description of Risks and Discomforts

Description of Benefits

Alternatives to Participating in the Research

Statement About Confidentiality Maintenance

Statement About Treatment and Compensation for Injury

Study Team Contact Information

Voluntary Participation and Withdrawal Information

*A Statement About Personal Health Information or Identifiable Biospecimens

What is Included in an Informed Consent?

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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 that are unforeseeable
- 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
- A statement regarding that biospecimens may be used for commercial profit, and if the subject will share in the profit
- Whether research will involve whole genome sequencing
- Statement if whether clinically relevant research results will be disclosed to subjects

What About HIPAA?

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HIPAA's purpose is to establish standards to protect individuals' 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.

What About HIPAA?

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UNC requires online HIPAA training for new employees and annual renewal training:

https://privacy.unc.edu/protect-unc-\information/hipaa/hipaa-training/

What About HIPAA?

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HIPAA Authorization

A form that a research participant signs to "authorize" access to their PHI for research purposes. This is separate from the informed consent document.

Limited Waiver of HIPAA

…is granted by the IRB/privacy board and allows access to key PHI in a limited manner (i.e., for recruitment purposes only). Usually followed by a full authorization.

Full Waiver of HIPAA

…is granted by the IRB/privacy board and allows full access to PHI without a signed authorization. But the use/disclosure of PHI must involve no more than a minimal risk to the privacy of individuals.

If you don't have HIPAA (in some form)...

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You can't look in someone's medical record **for any reason**

- Not for lab test results;
- Not to see if they've checked into a clinic;
- Not to verify medications;
- Not because you're curious about something;
- Not for feasibility;

If you need access to the medical record for you study- you must address HIPAA with the IRB through the IRB application.

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Informed Consent Discussion

Ensuring Participant Understanding

Remember the Scenario from Earlier?

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What was the drug being studied?

What was a risk?

Remember the Scenario from Earlier?

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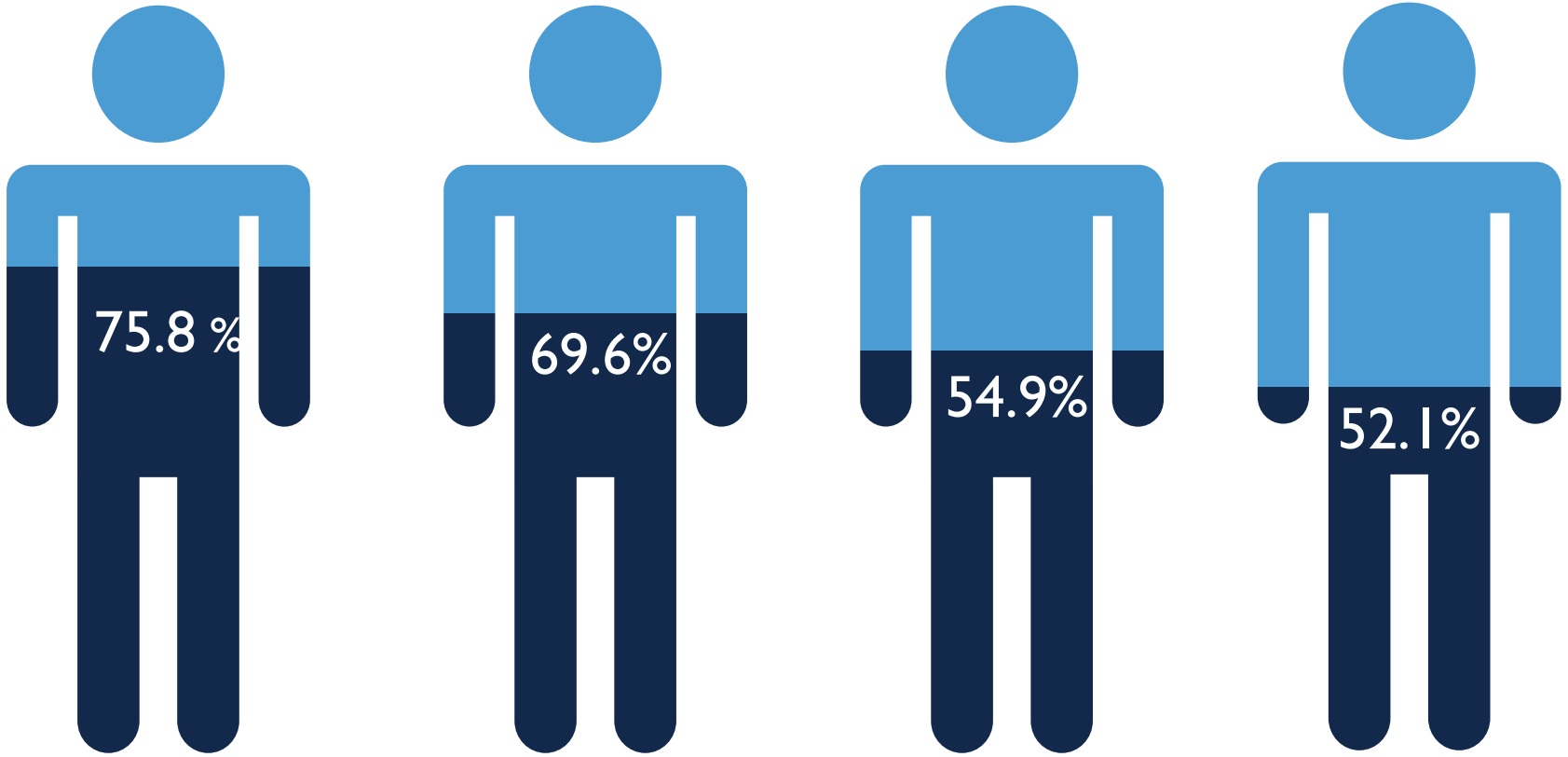

Participants' understanding of informed consent in clinical trials over three decades: systematic review and meta-analysis. Tam, 2014

Remember the Scenario from Earlier?

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What is the solution?

The Seven Questions:

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Who?

Who (Part 2)?

What?

When?

Where?

Why?

How?

Who?

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The Legal and Mental Capacity to Give Consent

Or

Legally Authorized Representative (LAR)

Who?

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Who can be a LAR?

Court Appointed Legal Guardian

Healthcare Power of Attorney

Durable General Power of Attorney

Who (Part 2):

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Investigator Must Delegate Responsibility

Must Have Received Appropriate Protocol Training

Must Have Consenting Process Knowledge

Must Speak the Language of the Subject, or Have a Reliable Interpreter

What?

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IRB Approved Consent

When?

Prior To....

- Conducting any procedures required by the research plan
- Entering a subject in a study
- Gathering any data about the subject

Where?

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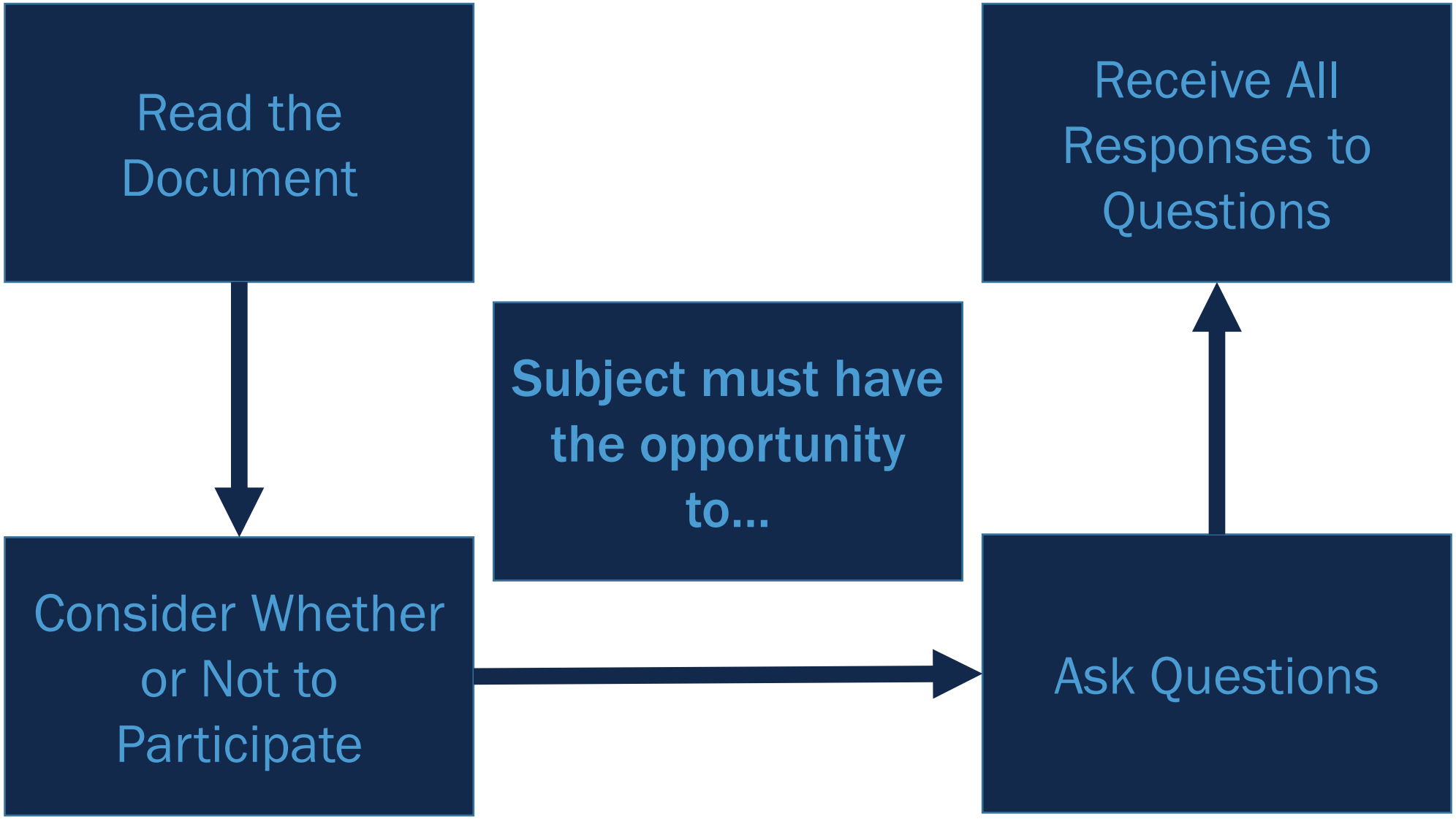

Why?

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The Purpose of Informed Consent...

How?

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- Minimize Coercion
- Pause to have the subject ask questions!
- Don’t talk too quickly
- Remember that the subject may not understand

After Signing Consent…

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Give the Subject a Copy of the Consent

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

After Signing Consent…

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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.

How?

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What Would You Do If...

A Potential Participant Says No?

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- 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 Potential Participant Seems “On the Fence”?

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- 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?

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- 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.

You Need Consent From Someone Who is Less Than 18 Years Old?

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- You need to obtain both an assent (what the child signs) and parental permission (what the parent signs).
- The IRB allows for different assent forms for different age ranges (i.e. 15-17 years old), so ensure you have the correct assent.
- If your participant turns 18 during the study, you will have them re-sign a normal consent.

A Clinic Staff Member Needs to See the Patient?

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- 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?

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- 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.


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