NEW iDEAS

Brain Imaging Study for Alzheimer's

Recruitment and Engagement Webinar

Consent Best Practices: Essential Elements and Cultural Considerations

ACR American College of Radiology

alzheimer's association

THE BRAINS BEHIND SAVING YOURS.

Presenters

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Consent Best Practices:

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Key Objectives

- Identify the Key Elements of Informed Consent
- Outline Informed Consent Best Practices
- Provide Tips and Tricks for Consenting in an Office Setting

Key Elements of Informed Consent

Key Differences between Medical and Research Consent

- “Consent for treatment” vs “consent for research”
- Consent for research includes 9 mandatory elements that must be discussed
- Consent is an **ongoing process** for research studies; not a one-time discussion
- “Therapeutic misconception”

Del Carmen MG, Joffe S. Informed consent for medical treatment and research: A review. The oncologist. 2005; 10:636-641.

The Informed Consent Document

- Provides a Summary of the Research
- Explains the Rights of the Participant
- Is designed to be a reference of what is expected

Informed Consent is More than a Signed Document

Provides Adequate Information	Information on risks/ benefits, procedures, et
Facilitates Comprehension	Utilizing teach-back method
Provides Adequate Opportunity for Questions	Stop and ask questions throughout, and provide consent before for review
Obtains Voluntary Agreement	Signature piece
Continues to Provide Information	This is an ongoing interactive process through the life of the study

Mandatory Elements

Description of Clinical Investigation

Risks/Discomforts

Benefits

Confidentiality

Alternatives to Research

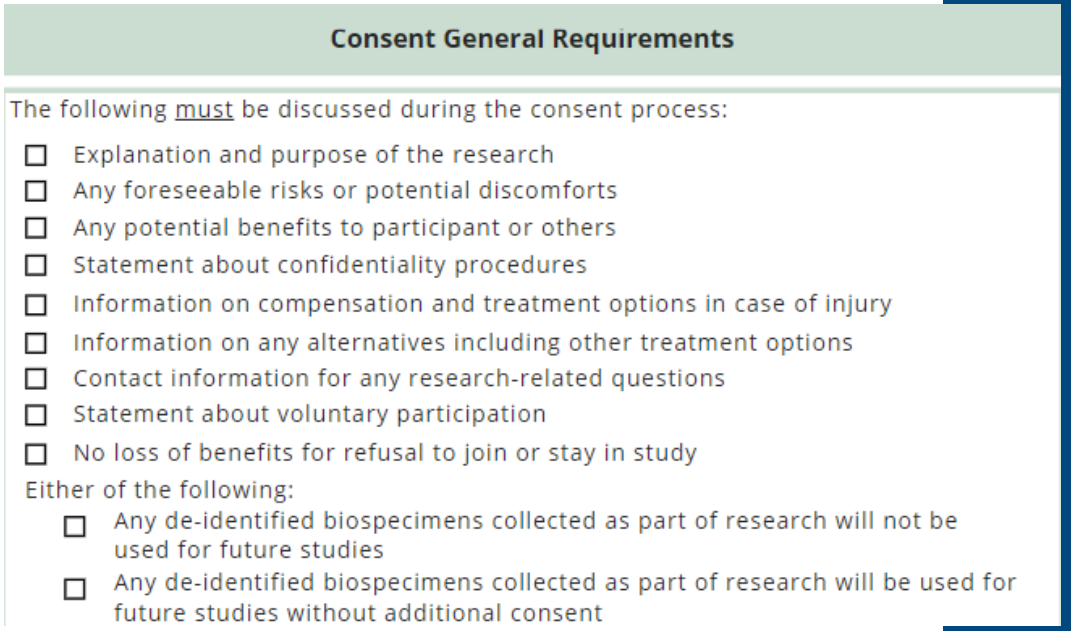
Identifieable PHI ./ Biospecimins Statement

Injury Compensation

Contacts

Voluntary Participations

Additional Requirements (When Appropriate)



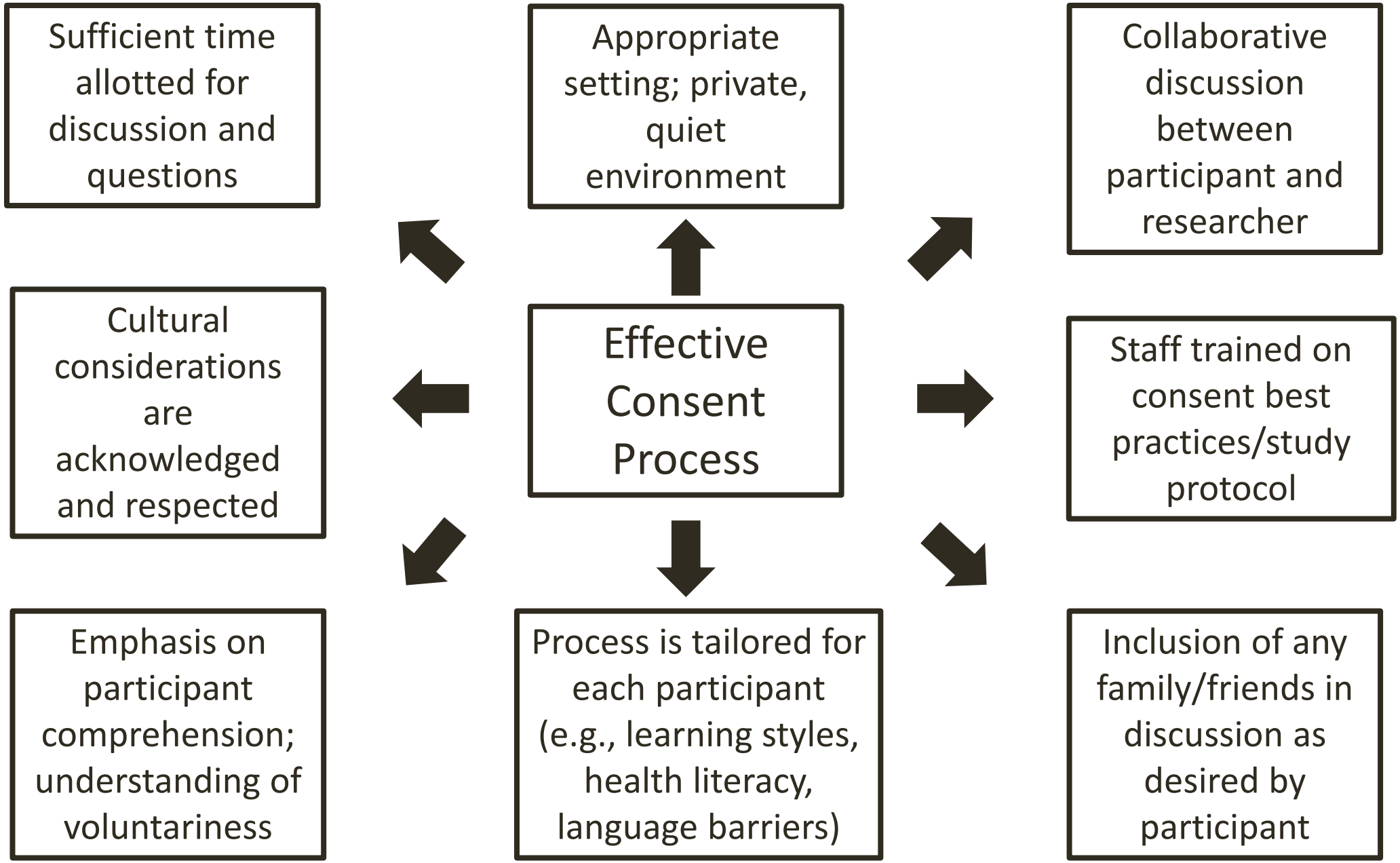
Consent General Requirements

The following must be discussed during the consent process:

- ☐ Explanation and purpose of the research
- ☐ Any foreseeable risks or potential discomforts
- ☐ Any potential benefits to participant or others
- ☐ Statement about confidentiality procedures
- ☐ Information on compensation and treatment options in case of injury
- ☐ Information on any alternatives including other treatment options
- ☐ Contact information for any research-related questions
- ☐ Statement about voluntary participation
- ☐ No loss of benefits for refusal to join or stay in study

Either of the following:

- ☐ Any de-identified biospecimens collected as part of research will not be used for future studies
- ☐ Any de-identified biospecimens collected as part of research will be used for future studies without additional consent



Lorell BH, Mikita SJ, Anderson A, Hallinan ZP, Forrest A. Informed consent in clinical research: Consensus recommendations for reform identified by an expert interview panel. *Clin trials*. 2015; 12(6): 692-695.

The Teach-Back Method

Tips for phrasing and follow-up

- Correct any misinformation
- Make sure participants are not simply repeating your words verbatim
- Try avoiding questions that can be answered with a simple yes or no
- **Remember:** this is about **comprehension** NOT memory

The Teach-Back Method

Examples for Teach-Back Approach for Consenting	
Purpose of research study	“Tell me in your own words what the purpose of this research study is” “What will happen if you agree to be a part of this study?”
Voluntariness	“What would happen if you refuse to take part in the study?
Benefits/Compensation	“What benefits would you expect by taking part in this study?” “What will you get in return for your participation?”
Risks	“What potential risks would you be taking by being in the study?”
Withdrawing from study	“What would happen if you decide to join the study today, but later decide you don’t want to be in the study?”
Confidentiality/Privacy	“Who will be allowed to see the information/data we collect from you in the study?”
Contact Information	“Who should you contact if you have any concerns or questions about the study?”

Legally Authorized Representative

Tips for documentation

- LAR section is only completed when the participant does **not** have decisional capacity
- The authorized signature/initial in this case becomes the LAR, not the participant
- The LAR signature/initial must then be used throughout the ICD
  - Depending on institutional guidelines, assent should then be completed for the participant

Tips and Tricks for Consenting in an Office Setting

Find a Quiet Empty Room

If you must, you can use the exam room, just make sure they are sitting in a chair and not on the table

Make sure they are comfortable

Maybe offer a cup of water, tea, coffee

Use a noise machine

Will help block others from hearing your conversation

Don't wear a lab coat

This can create a situation of undue influence

Allocate enough time

Remember that this is a conversation

Allow inclusion of any family, friends, advisors

Participant is notified to bring any family/friends they wish to be a part of the consent discussion

Utilize multiple methods of communication

Tailor the consent discussion for each participant (use tables, graphs, images, videos)

Provide Consent Form before visit

This allows time for review beforehand

Populations Requiring Additional Protections

- Fetuses, Pregnant Women, and Human In Vitro Fertilization
- Prisoners
- Children
- **Cognitively Impaired**
- **Racial and Ethnic Minorities and Underrepresented Populations**

- **Additional Resources:**

- MRCT Consent Guide
- Article - Barriers to change in the informed consent process
- Rochester Informed Consent Guide
- Hopkins Informed Consent Guide
- AHRQ Informed Consent Toolkit

- **REFERENCES**

- Del Carmen MG, Joffe S. Informed consent for medical treatment and research: A review. The oncologist. 2005; 10:636-641.

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Best Practices for Consenting Minorities

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Overview

- Outline current challenges in consenting racial and ethnic minority groups
- Explore tailored strategies that can be used for consenting minority populations
- Highlighting additional resources

Underrepresentation in clinical research

- Black or African American individuals represent 13.4% of the population, yet the FDA reports **show that only 5% of clinical trial participants** come from this demographic.
- Hispanic or Latino heritage individuals, represent almost one fifth (18.1%) of the population yet **only 1% of trial participants.**
- Other well-known, documented disparities in clinical trial participation include **lack of awareness** and education around clinical trials, **fears of mistreatment**, financial constraints and **costs of participating**, limited **access to study referrals**, and **reduced opportunities to participate.**
- It's important to include diverse populations to understand the generalizability of study findings

Diversity in Clinical Trials. (n.d.). *Clinical Research Pathways*. Retrieved July 8, 2021, from https://clinicalresearchpathways.org/diversity/

Health care discrepancies in Minority populations

- Racial minorities often wait longer for appointments, are afforded fewer privileges, **providers spend less time** with them asking and answering questions and are often being spoken to in a **condescending or paternalistic tone** from their providers.
- **Uncertainty and time** pressure surrounding treatment may encourage provider reliance on stereotypes for decision-making especially since medical training is **focused on group level information** like population risks, which can lead to stereotyping.
- Extensive knowledge of scientific data may create a strong belief of personal objectivity, **promoting bias in decision-making**.
- A recent article in JAMA Network found that **symptoms of burnout** were associated with higher levels of racial bias in resident physicians.

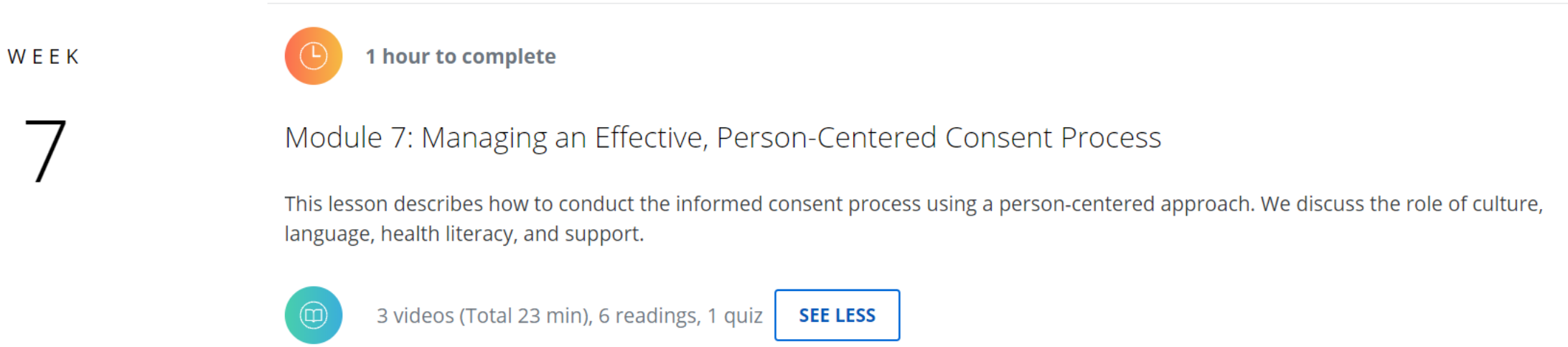
Lauer-Arnold I. Health care disparities, provider bias, and provider burnout. The Brown University Child and Adolescent Behavior Letter. 2019;35(10):1-6. doi:10.1002/cbl.30412

Chapman EN, Kaatz A, Carnes M. Physicians and Implicit Bias: How Doctors May Unwittingly Perpetuate Health Care Disparities. J GEN INTERN MED. 2013;28(11):1504-1510. doi:10.1007/s11606-013-2441-1

What We Know About the Participants

- **Culture, values, and beliefs** can have a large impact on their ability to decide in enrolling in a trial.
- Many participants are **misinformed about research** and have incomplete comprehension of information specific to research studies.
- The **issue of minority trust** in research is an important factor to consider when evaluating ways to improve the informed consent process.
- Racial minority participants often have challenges advocating for themselves, particularly in environments with varying power dynamics
- There is often a lack of familiarity with research concepts.

Module 7: Managing an Effective, Person-Center Consent Process



Goal: To teach individuals how to conduct the informed consent process using a person-centered approach. We discuss the role of culture, language, health literacy, and support.

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Trust Building Tips to Enhance the Consent Process

Engage	Engage family, caregivers, and patient advocates
Coordinate	Coordinate with trusted providers
Utilize	Utilize supplemental materials
Allow	Allow adequate space and time for authentic dialogue
Acknowledge	Acknowledge historical context surrounding consenting Black and Latinx populations
Highlight	Highlight areas in the consent form that encourage participant advocacy
Focus on	Focus on individual experience through perspective taking
Note	Note the protections in place to safeguard patient information
Practice	Practice strategies to reject automatic response as a care provider
Increase	Increase cultural competence through implicit bias training

Managing an Effective, Person-Centered Consent Process

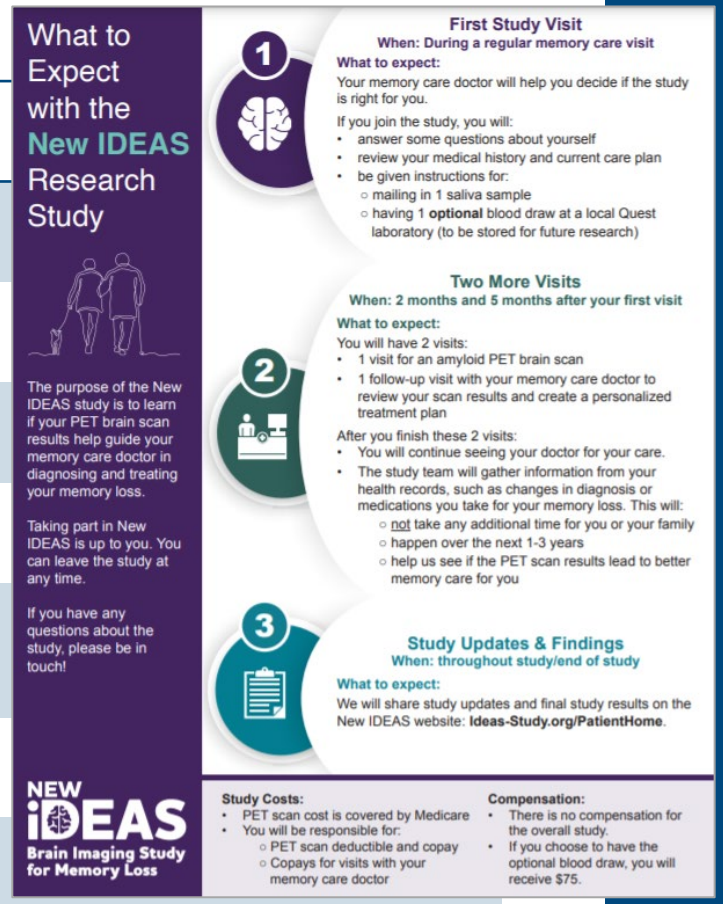
What have we heard from participants and community members?

- Community members prefer **talking with other trial participants** at higher rates than what researchers provide.
- Community members **prefer the use of video** to explain the study at higher rates than researchers provide.
- Researchers **often read aloud** the consent form by community members find this less helpful.

Managing an Effective, Person-Centered Consent Process

Tactics and Strategies to Use During the Consent Process

- Use plain language, include brief summaries, and use pictures
- Be honest and create a space to promote honesty
- Provide adequate time for people to make an informed decision
- Make sure that they can make well informed decisions
- Provide supportive resources
  - Consider English proficiency as you are developing these resources
- Make sure that the translated materials support understanding
- Engage language interpreters
- Acknowledge health literacy and ensure that study materials are written at a 5th grade reading level



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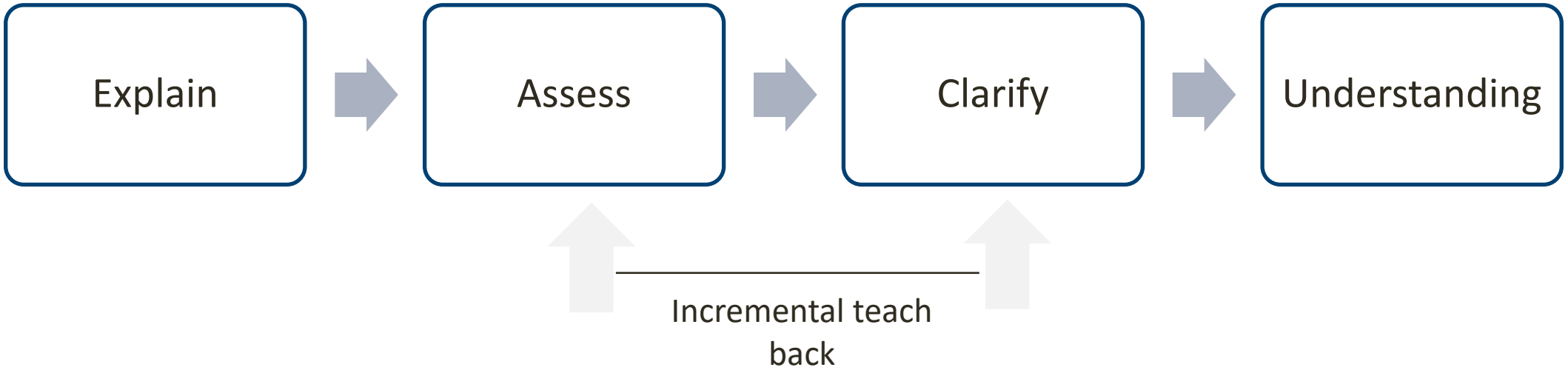
Assessing Understanding During the Consent Process

- Use open ended questions to make sure that there is a clear understanding between you and the participant
- Ensure they understand the questions through incremental teach back



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Important Concepts to Explain

4 common concepts that are difficult to understand

- How randomization works
- How a placebo is used
- Potential benefits and risks
- The likelihood of personal benefit

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Additional Resources

- Trial Innovation Network (TIN) toolkit
- Diversity in Clinical Trials from Brigham and Women's Hospital
- Engaging Racial And Ethnic Minority Patient Populations in Covid-19 Clinical Trials
- The Art of Recruitment
- Faster Together – Enhancing Recruitment of Minorities in Clinical Trials

Questions