Health Literacy Initiatives: Incorporating the Teachback Method into the Consenting Conversation

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Objectives

1. Discuss the issue of health literacy
2. Detail a few HRPP policies on consent
3. Provide strategies for incorporating teachback and using it to assess cognitive capacity

Key Abbreviations

- **HRPP** = Human Research Protections Program
- **IC** = informed consent
- **ICF** = informed consent form
- **LAR** = Legally Authorized Representative
- **PI** = Principal Investigator
- "**Subject**" includes subject, subject's LAR, or subject's parent(s)/legal guardian(s)

The Nature of the Problem

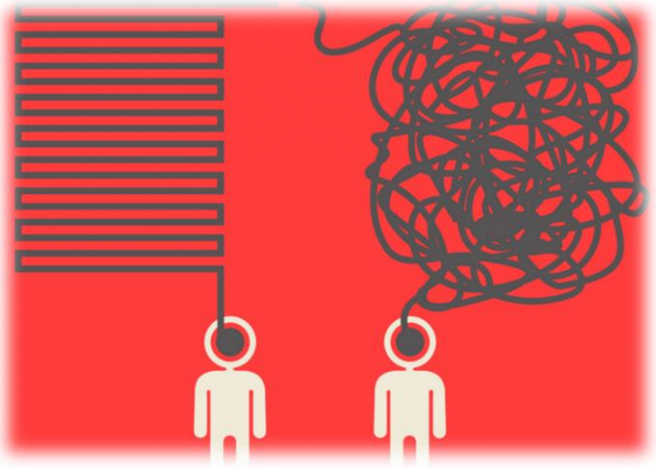
Health Literacy Defined

Are you confused about health information? You're not alone

Lisa Fitzpatrick | TEDxMidAtlantic

What is health literacy?

The Patient Protection and Affordable Care Act of 2010, Title V, defines health literacy as:



"the degree to which an individual has the capacity to obtain, communicate, process, and understand basic health information and services to make appropriate health decisions"

How does health literacy affect me and our studies?

- Only **12%** of U.S. adults **have proficient health literacy**
- Limited health literacy affects adults in **all racial and ethnic groups**
- Even high school and college grads can have limited health literacy
- Compared to privately insured adults, **publicly insured and uninsured adults had lower health literacy**

America's Health Literacy: Why We Need Accessible Health Information. An Issue Brief From the US DHHS. 2008.

Health Literacy

UAB School of Nursing, 2014

A Reminder of a Few Consent-Related BMC/BUMC Policies

Adapted from the Human Research Protections Program (HRPP) website. Full text accessible at www.bumc.bu.edu/ohra/hrpp-policies/hrpp-policies-procedures/

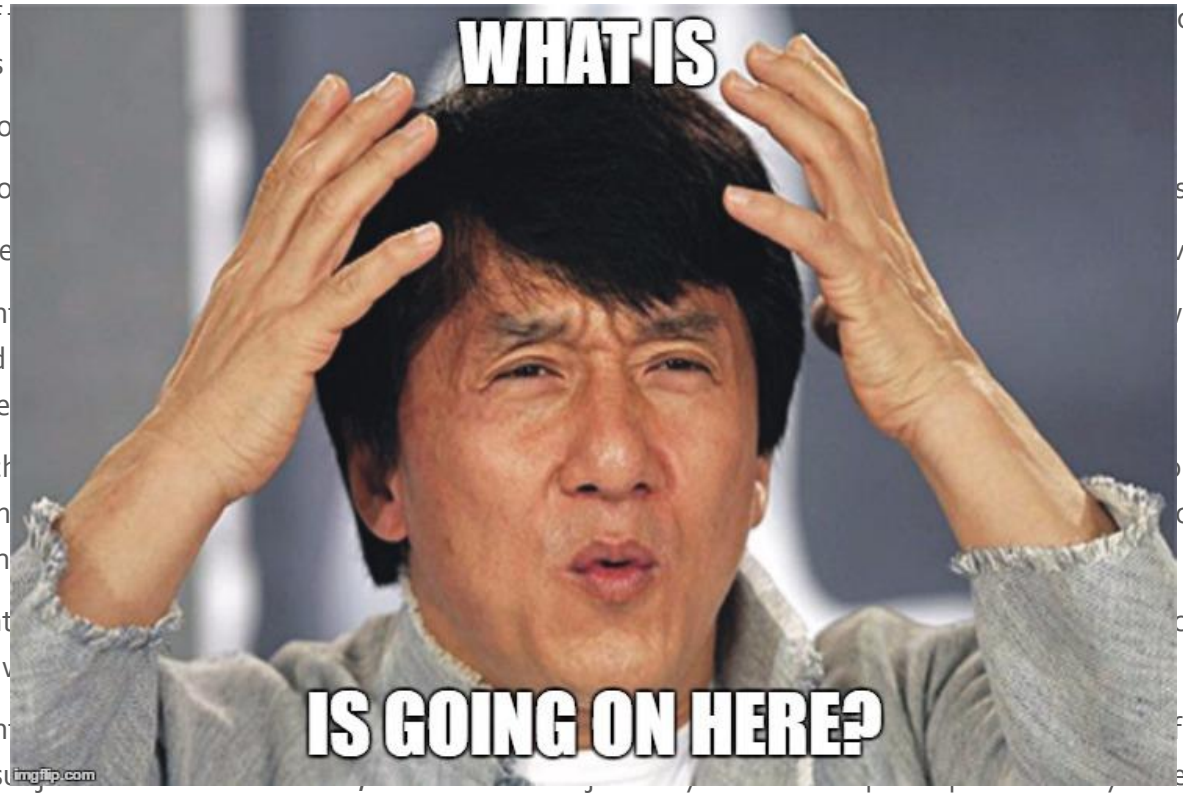
8.2.1.1 General Requirements for Informed Consent *(adapted)*

- Consent information provided to potential subjects for research initially approval on or after July 19, 2018 must:
  - Provide the information in **sufficient detail** that a reasonable person would want to have in order to make an informed decision about whether to participate in the study; and
  - Organize and **present the information in a way that facilitates understanding** of why one might or might not want to participate; and
  - Begin with a **concise and focused presentation of the key information** that is most likely to assist in understanding the reasons why one might or might not want to participate in the research.
- The prospective subject must be provided with **sufficient opportunity to discuss the information** provided to them and to consider whether or not to participate in the research. The consent process must minimize the possibility of coercion or undue influence. The information that is given to the subject shall be in **language understandable to the subject**.

8.2.1.2 Basic Elements of Informed Consent *(adapted)*

Basic elements of IC that must be provided to each subject unless IRB has waived or altered the consent process:

1. A statement that the study involves research, an explanation of the purposes of the research and the expected duration of t on of any procedures
2. A descriptio
3. A descriptio search;
4. A disclosure vantageous;
5. A statemen ill be maintained others, as appropriate
6. For research r an explanation onsist of, or where furth
7. An explanat ch subjects' rights, and v
8. A statemen f benefits to which the su e without penalty or loss of benefits to which the subject is otherwise entitled.



(This list continues on line based on study category)

4.5.1 Planned Inclusion of Non-English Speaking Subjects *(adapted)*

Special protections are required when potential research subjects do not speak English. Informed consent **materials** must be **presented in language understandable to the subject** and consent must be documented in writing unless waived by the IRB (see Sections 8.4.2 and 8.4.3).

Whenever possible, the documentation must be in the form of an informed consent **written in a language understandable to the subject that embodies all of the elements of informed consent** (see Section 8.2).

8.4.6 Informed Consent for Limited- and Non-Readers *(adapted)*

- Potential subjects are **considered to be limited- or non-readers when they ask to have the consent form read to them** during the consent process or otherwise verbally indicates that they are having difficulty reading the consent form. If the study does not exclude limited- and non-readers and is greater than minimal risk, the PI must either **plan to have an impartial witness** who is present throughout the consent process or propose some other method, such as a quiz or a **"teach-back" process**, to ensure comprehension. This latter approach can be used when consent is obtained just from limited- or non-readers, or **can be used for all subjects**. If the research is being performed according to the standards of the ICH-GCP, an **impartial witness** is required for obtaining consent from limited- and non-readers.

The Teachback Method

How to synthesize your knowledge of health literacy with a desire to improve patient understanding

What is teach-back?

- A strategy to improve the researcher's ability to explain the ICF content in a **clear way**
- An opportunity to facilitate **understanding** of why one might or might not want to participate
- A tool to assure that the prospective subject is provided with sufficient opportunity to **discuss** the information provided to them and to consider whether to participate in the research

How to start the teach-back conversation

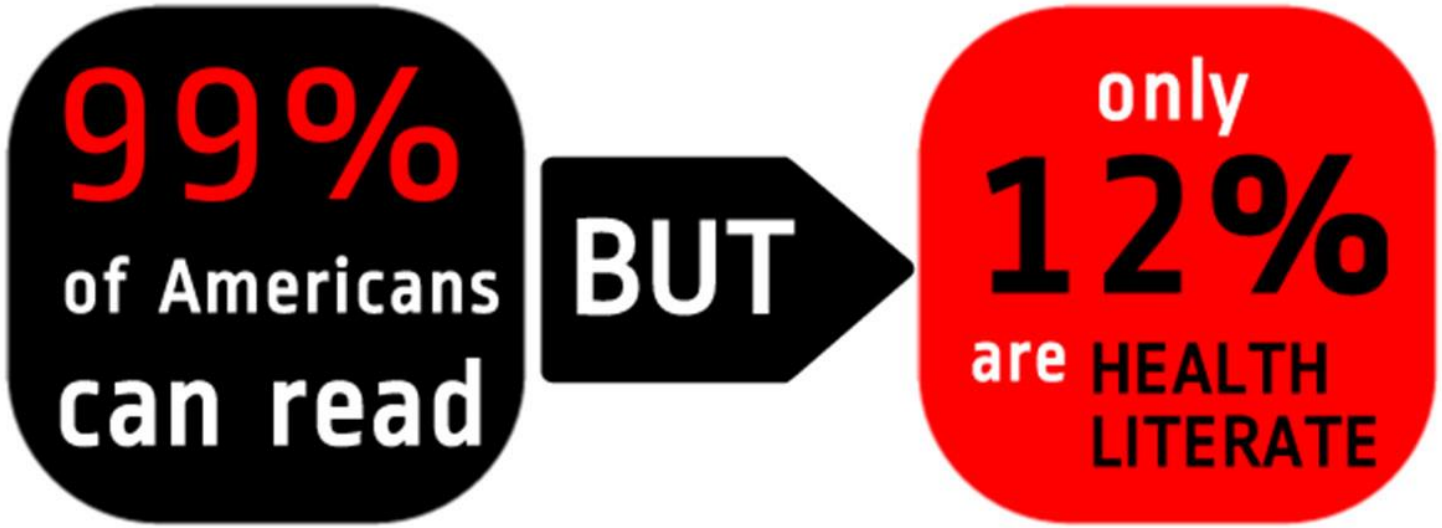
- Ask patients to demonstrate understanding (i.e., how well ***you*** explained it to them), using their own words:
  - "I want to be sure I explained everything clearly. Can you please explain it back to me so I can be sure I did?"
  - What will you tell your husband about the research study you are participating it?
  - "We've gone over a lot of information, a lot of things that this research study involves. In your own words, could you please tell me what you will be doing during this study?"

Your Turn!

- Partner with someone you don't know very well
- Read the content of the index card to your partner then use the teach-back method to assess how well they understood
- Do not let them read the card!
- Switch

What if the subject couldn't successfully explain?

- Re-phrase if the subject is not able to repeat the information accurately.
- Ask the patient to teach back the information again, using their own words, **until you are comfortable they really understand it.**
- Be encouraging!
  - **DO say**: I'm sorry I didn't explain it well enough! [Paraphrase the part they struggled with]. Could you tell me in your own words what that means you'll be doing?
  - **DON'T say**: "No, you're wrong"
- If they still do not understand, consider other strategies.
  - Assess appropriateness of consenting them to the study



What else can we do?

Actionable items for change

Assess readability of ICF before submitting for IRB approval

- GCP: Goal of **8th grade or less** for ICFs[1,2]
- Indices
  - SMOG (Simple Measure of Gobbledygook)
  - Flesch-Kincaid Grade Level Score
  - Indicate the **years of education required** for a person to understand the text
- Flesch-Kincaid Reading Ease
  - Higher number is better![3] Aim for ≥80

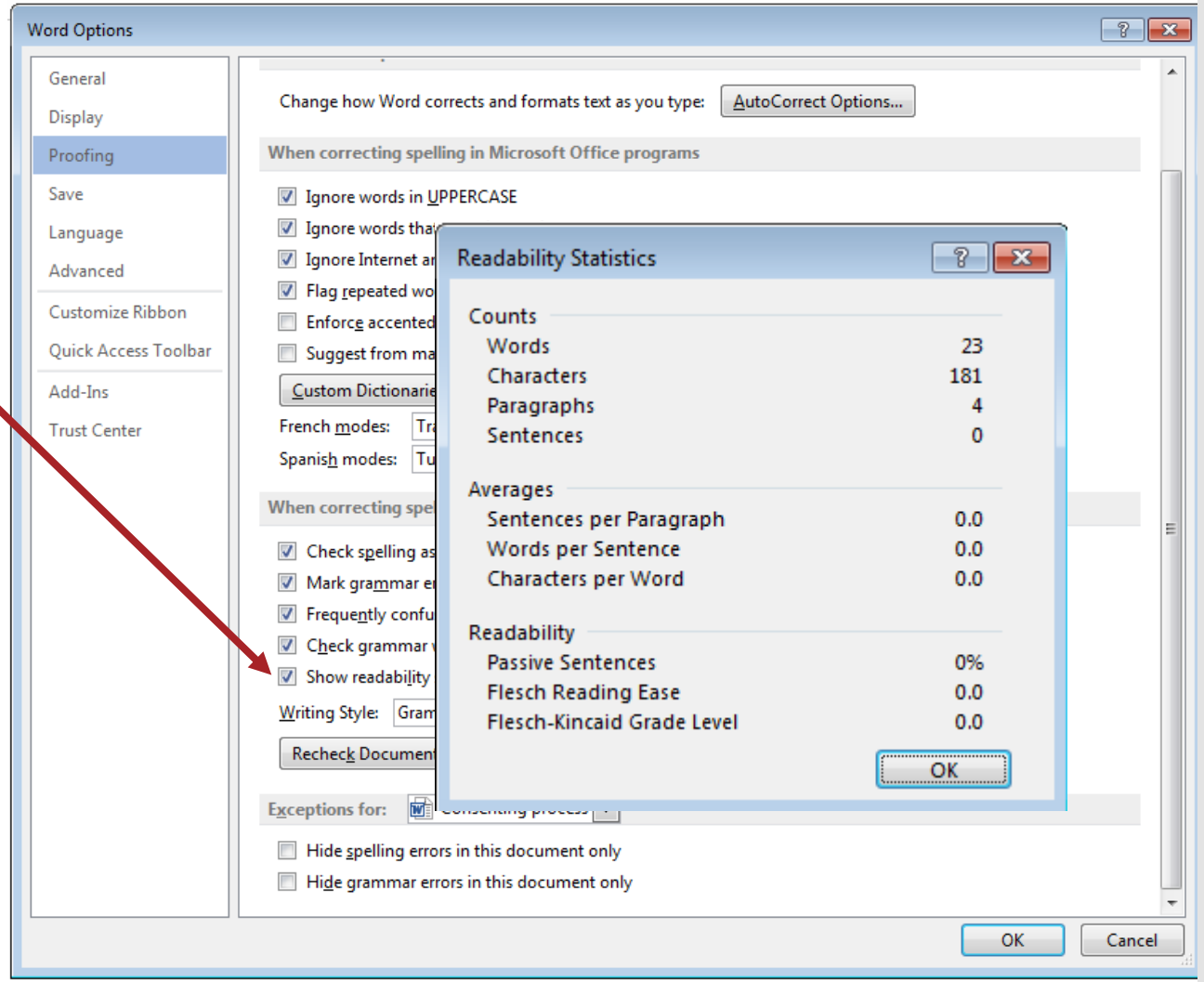
[1]Landi N. An examination of the relationship between reading comprehension, higher-level and lower-level reading sub-skills in adults. Read Writ. 2010;23:701–17. [2]Informed Consent Information Sheet. FDA. 2018.. [3]Test your document's readability. Microsoft Office. 2018.

Finding Readability Scores

Microsoft Office

- Options
- Proofing
- Readability statistics

Next time you run "Spelling and Grammar," readability will show



Additional Suggestions from IRB websites

Simonds VW, Garroutte EM, Buchwald D. Health literacy and informed consent materials: designed for documentation, not comprehension of health research. *J Health Commun*. 2017;22:8, 682-691.

Table 4. Health literacy criteria addressed by Institutional Review Board websites.

Health literacy criteria provided	Sites *N*	Example text from IRB websites
Reading level		
Guidance on grade reading level	8	Consent documents should be written at an 8th grade reading level or less for the average adult population.
Content		
Guidance on the purpose of the document	8	Start with an introductory sentence describing the primary purpose of the research as stated in the protocol: State what the study is designed to discover or establish.
Literacy demand		
Active, direct writing style	5	Whenever possible use active voice and break up the text into short straightforward
Personal, conversatio		
Common, explicit w and specific in me		
Simple sentences		
Explain or clarify dif		
Numeracy		
Use of numbers or n		
Terms should be defi		
Graphics		
Use of charts, graphs		
Layout		
General layout and organization	5	Leave a 1-inch margin around the entire document. Use of subheadings, bulleted lists, tables, flow charts, etc. to improve communication and readability.
Adequate white space	2	Layout balances white space with words and graphics.
Visual cueing devices	3	Underline, bold, or boxes (rather than all caps or italics) to give emphasis.
Size of font	6	12 point at least, and consider larger given audience. Easy to read.
Type of font	3	Use black Arial or similar font, preferably 12-point size, or larger when appropriate for the study population.
Use of headings	4	Titles, subtitles, and other headers help to clarify organization of text. Section headings should be in question format.

Summary

- 8th grade reading level or less
- Active voice
- Conversational style
- Lay terms
- Photos and graphics
- Section headers in question format

Questions?

Application of the Teach-Back Process: Consent Capacity in Research

Jane Mwicigi, MPH

BU Alzheimer's Disease Center

Investigators' Ethical Responsibility In Research

- To disclose information to a potential research participant.

- To ensure that the participant has the capacity to reach a decision on the basis of the information provided.

Special Challenges of Alzheimer's Disease (AD)

- A dreadfully feared debilitating disease
- There's no effective treatment for AD
- The participant's wish to make an impact at beating the disease for themselves, their children and society
- The desperate wish of the afflicted to try a medication that may offer a potential benefit – this need may make them overlook the risks

Standard of Care vs. Research

SOC treatment aims to maximize a patient's good.

Research is designed to create generalizable knowledge. It is not the same as SOC.

- Research may expose participants to some procedures whose risks and burdens are not justified by the benefit to each participant's health and well-being
- The benefit is the importance of the knowledge that the study is designed to produce

BMC and BUMC HRPP Policies and Procedures

9.5.1 Additional Requirements for Decisionally-Impaired Persons

The use of decisionally-impaired persons as research subjects presents a risk that their disability may compromise their capacity to understand the information presented during the consent process and their ability to make a sound decision as to whether to participate in the research.

For this reason, additional protections are required. The PI must indicate in the submission whether any subject who is cognitively impaired will be recruited, and if so, **must describe how the subjects' ability to consent will be assessed**, how LAR will be identified, and how the consent and assent process will prevent undue influence and coercion.

The PI explain why inclusion of decisionally-impaired subjects is necessary to answer the study question. If the study population is expected to include persons whose cognitive capacity may fluctuate during the course of the research, the PI must describe plans for assessing cognitive capacity and obtaining consent from the subject to continue in the research when appropriate.

BMC and BUMC HRPP Policies and Procedures

The IRB will approve research on decisionally-impaired persons when:

- The **consent/assent process** adequately protects the rights and welfare of these subjects; and
- The PI has adequately justified the **inclusion of this vulnerable population as necessary to answer the study question,** not merely as a convenience for recruitment; and
- The risks fall into one of the following categories:
  - No greater than minimal risk; or
  - Greater than minimal risk and the research holds out the prospect of direct benefit to the subjects; or
  - **Greater than minimal risk with no prospect of direct benefit to the subjects** when **BOTH** of the following are true:
    - The knowledge likely to be gained through the research will improve the understanding of the condition, disease, or behavior affecting the participant population; and
    - The risks to subjects, including the risks of foregoing available alternative treatments, are not substantially greater than those associated with the available alternative approaches.

Assessing Consent Capacity is in line with Belmont ethical principle

- Of respect for persons and protecting their autonomy in research.

Disadvantages of Clinical Instruments Used to Assess Decisional Capacity

- Require formal psychological evaluation by clinicians-MD or Neuropsychologist.
- The questions focus on various cognitive abilities.
- Require considerable time to administer → may not be practical in screening research subjects

https://jamanetwork.com/journals/jamapsychiatry/fullarticle/481615
https://jamanetwork.com/journals/jamapsychiatry/fullarticle/482397
https://ajp.psychiatryonline.org/doi/full/10.1176/ajp.156.9.1380

Move from Decisional Capacity to Consent Capacity

- Efforts to develop a more practical and direct approach.

- Methods that involve asking participants questions about consent-related aspects of a study and re-educating to enhance understanding
  - ➢ the teach-back method

- Consent capacity ≠ “decision-making capacity.”

Consent Capacity

- An adult's ability to understand information relevant to making an informed, voluntary decision to participate in research.

https://grants.nih.gov/grants/policy/questionablecapacity.htm

Teach-Back as Remediation for Impaired Consent Capacity

- A two-part consent process:
- Consent information is presented
- a questionnaire is administered to determine the individual's understanding.
- The process may be enhanced by use of IRB approved consent tools such as videos and flip charts.
- Subject should have consent form to refer to as needed.

Person discussing consent evaluates 4 areas

1. Subject's understanding of the study
   - Consent sections to focus on - purpose, procedures and risks.
2. Subject's appreciation of consequences of participation
   - This is research, any benefits or if there's none, any changes to participant's current and future treatment and if none clarify, confidentiality and access to collected data.
3. Subject's reasoning/decision process
   - Participant should be aware of available alternatives, should be clear doesn't have to participate.
4. Participant's ability to make a choice
   - Clear expression of choice for or against participation.

Judgement Call

- After the teach-back intervention the person conducting the consent discussion should be satisfied that subject has the capacity to consent

OR

- Person conducting consent decides subject does not have the capacity → LAR would sign consent and subject will assent.

- Document the process in subject's progress notes.

Refer to IRB guidance on who can be a LAR.

BMC and BUMC HRPP Policies and Procedures

7.2.2.12.5 Consent by Substituted Judgment Information

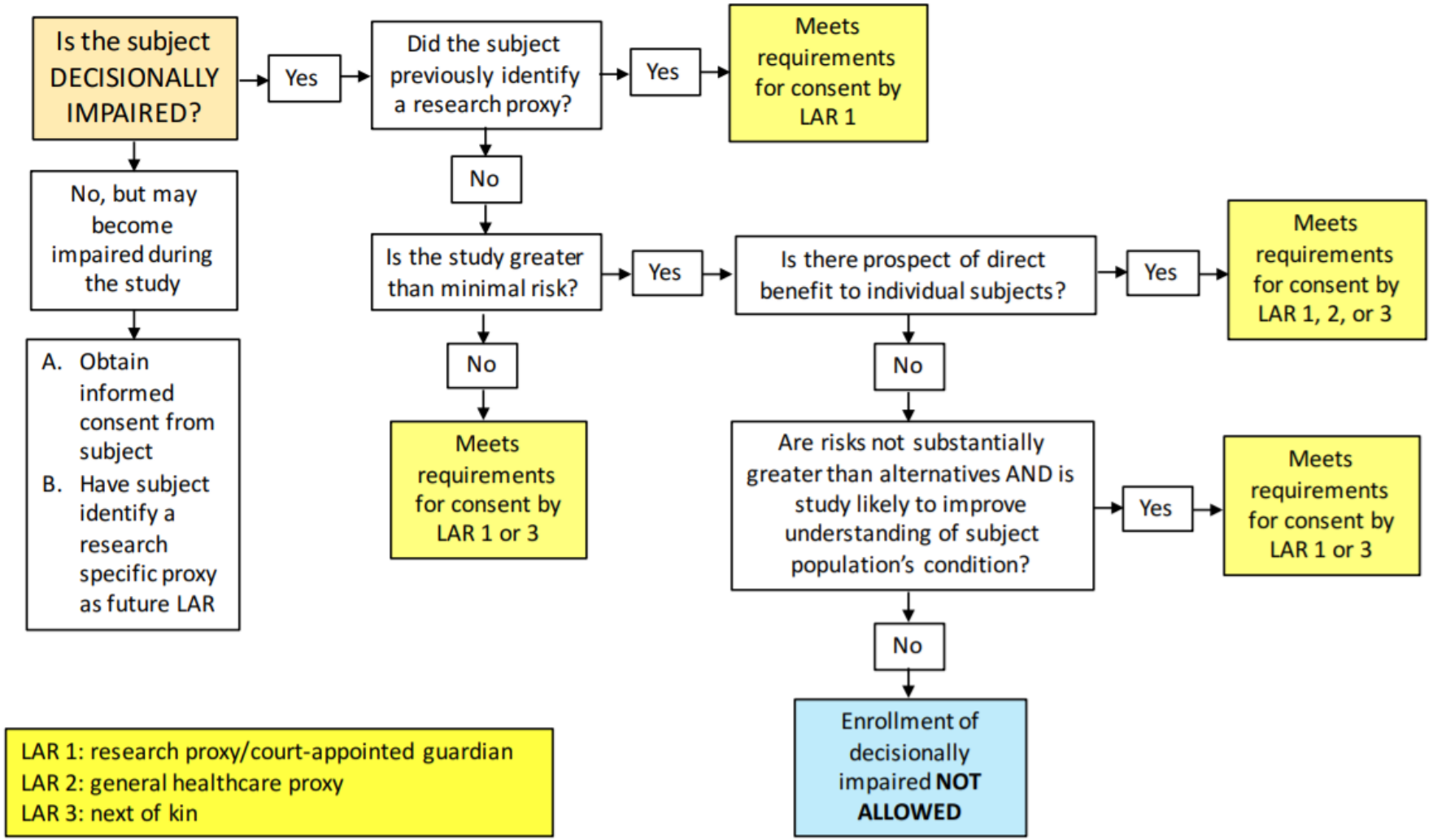
The submission information if the study involves obtaining consent from legally authorized representatives for cognitively impaired subjects must include a description of:

- **The process for ascertaining the capacity of potential subjects to provide consent** for themselves; and
- The process for determining who may provide **consent** for decisionally impaired subjects

Consenting Decisionally Impaired Adults in Research

Only allowed when inclusion is necessary to answer the study question

Consent is obtained from a Legally-Authorized Representative (LAR), assent is obtained from the subject



Summary

- Teach-back process enhances understanding of a consent .
- It may take more time but is worth the effort.
- It is important to utilize teach-back not only for ethical reasons but to acknowledge and respect participants with cognitive difficulties.
- Teach-back method promotes autonomy of research participants.

Thank you.

Read the sections of study consent provided

- What questions can you ask to verify understanding, appreciation and reasoning?
  1.
  2.
  3.

- Clarify information guided by the responses.