Plain Language, Teach-back, and Guidance for Re-consent

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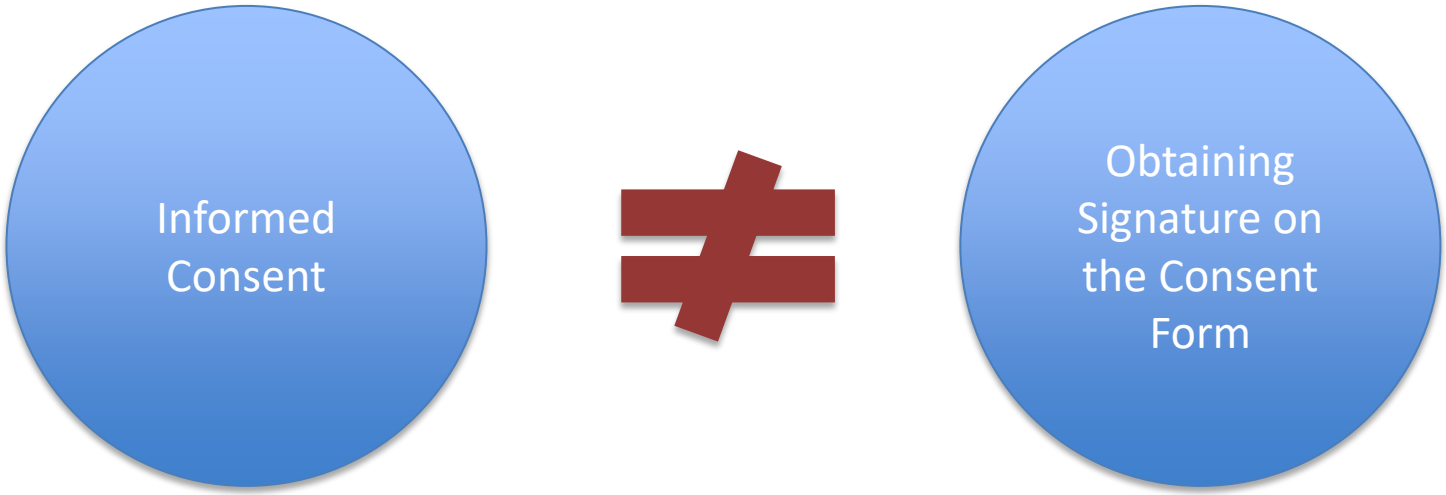
Session Objectives

The Informed Consent Process

- Describe best practices in obtaining informed consent.
  - Use of plain language
  - Use of the teach-back method
- Review Reconsent best practices

Introduction



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Informed Consent

- Informed consent involves providing a potential subject with adequate information to allow for an informed decision about participation in the clinical investigation
- Facilitating the potential subject's comprehension of the information
- Providing adequate opportunity for the potential subject to ask questions and to consider whether to participate
- Obtaining the potential subject's voluntary agreement to participate
- Continuing to provide information as the clinical investigation progresses or as the subject or situation requires.

FDA Guidance: “Informed Consent Guidance for IRBs, Clinical Investigators, and Sponsors”

Conversation

(21 CFR 50.20.)

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Health Literacy

- Defined as the ability to:
  - Obtain, process and understand basic health information and services
  - Make informed health care decisions (act on information)
  - Access/navigate health care systems

Centers for Disease Control and Prevention, 2021

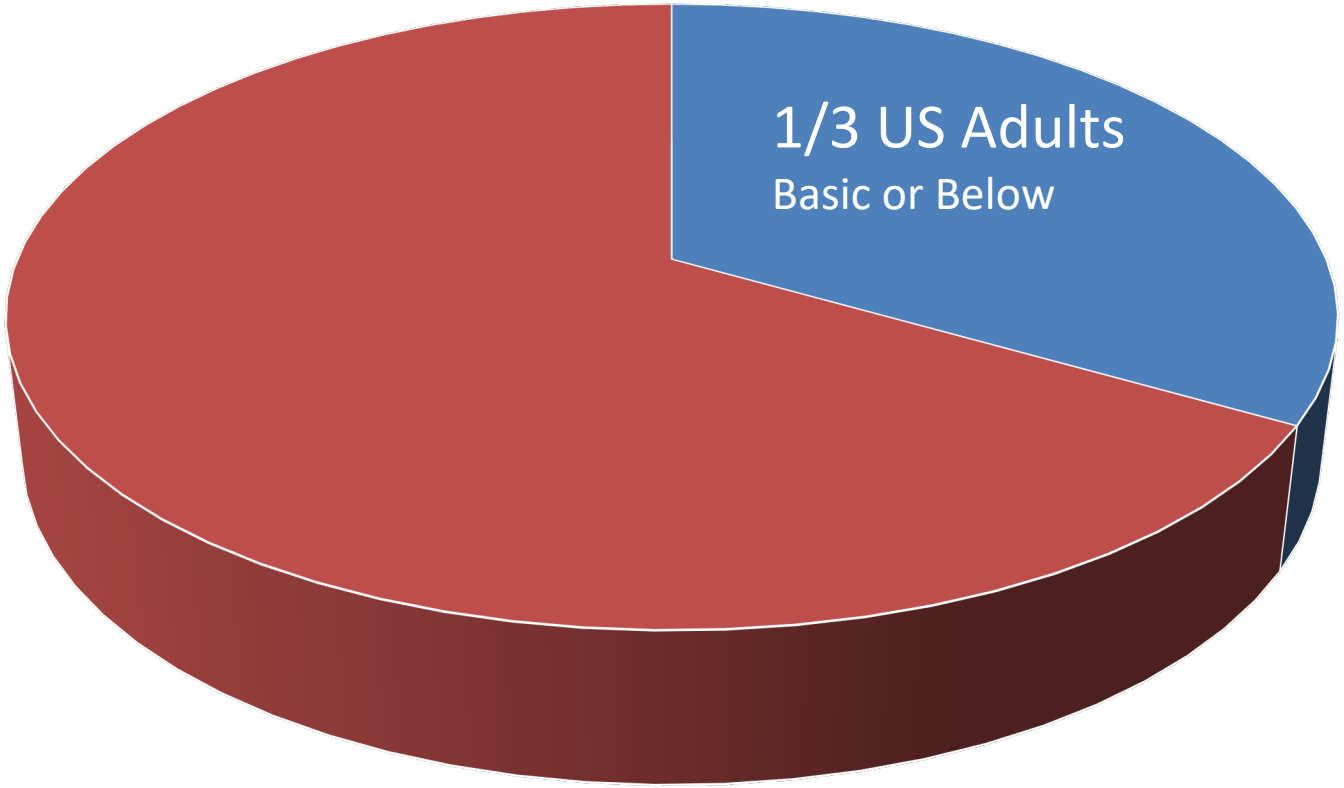
Poll

True or False?

Healthcare professionals can determine an approximate literacy level of their patients from information on their education and occupation?

FALSE

Health Literacy



Kutner, M, Greenberg, E, Jin, Y, and Paulsen, C, (2006) *The Health Literacy of America's Adults: Results From the 2003 National Assessment of Adult Literacy* (NCES 2006-483). U.S. Department of Education, Washington, DC, National Center for Education Statistics.

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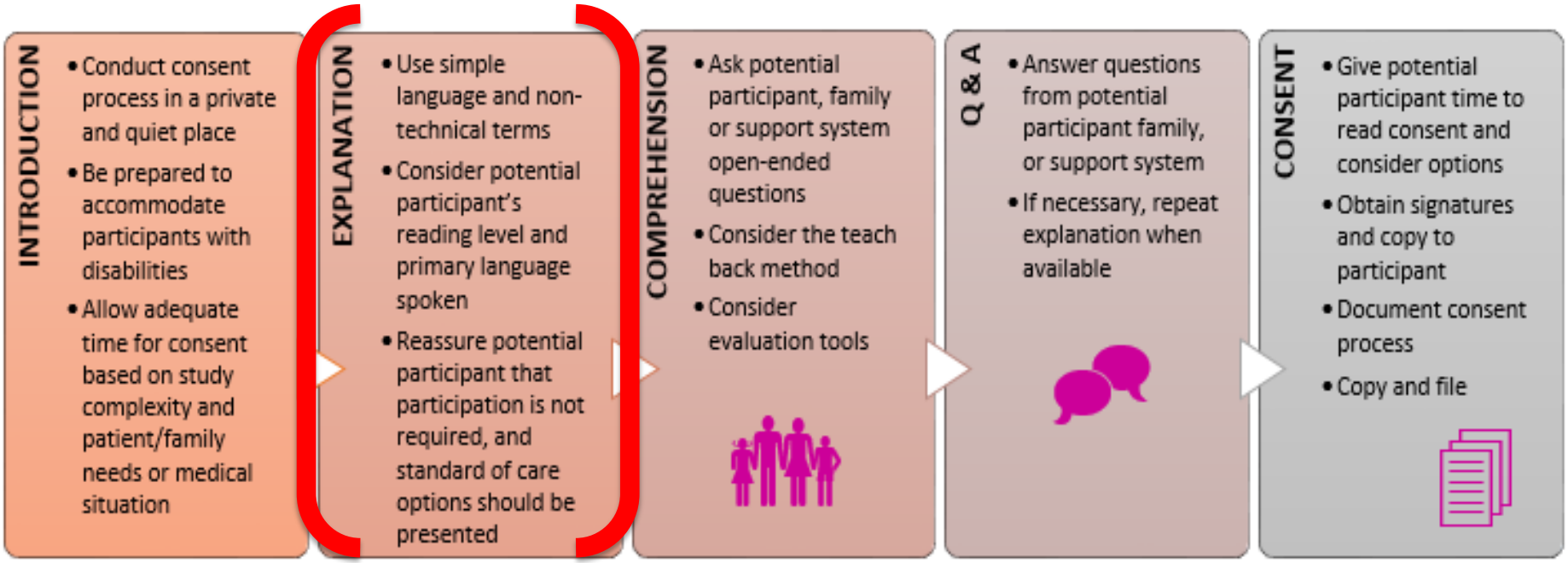
Red Flags for Low Literacy

- Frequently missed appointments
- Incomplete registration forms
- Non-compliance with medication
- Unable to name medications, explain purpose or dosing
- Identifies pills by looking at them, not reading label
- Unable to give coherent, sequential history
- Ask fewer questions
- Lack of follow-through on tests or referrals

Steps for Obtaining Informed Consent



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Plain Language

- A way of communicating that everyone in your audience can easily understand
- Relevant to the reader/listener
- Clear and concise
- Easy to follow
- Conversational and direct
- Designed to be inviting and help readers find important information

Plain Language Association International.
http://plainlanguagenetwork.org/index.html

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Explanation

- Assess the participant
  - Primary language spoken
  - Reading level – GU IRB 8th grade or lower
- Non-technical terms should be used

Examples

Glomerulonephritis

inflammation of the tiny filters in your kidneys

Hyperlipidemia

a condition in which there are high levels of fat particles (lipids) in the blood.

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Glossaries of lay terms

- http://irb.ufl.edu/irb01/forms/glossary.html
- https://www.magiworld.org/IcfGlossary
- *http://kidshealth.org/kid/word/*
- https://researchcompliance.stanford.edu/panels/hs/forms/definitions

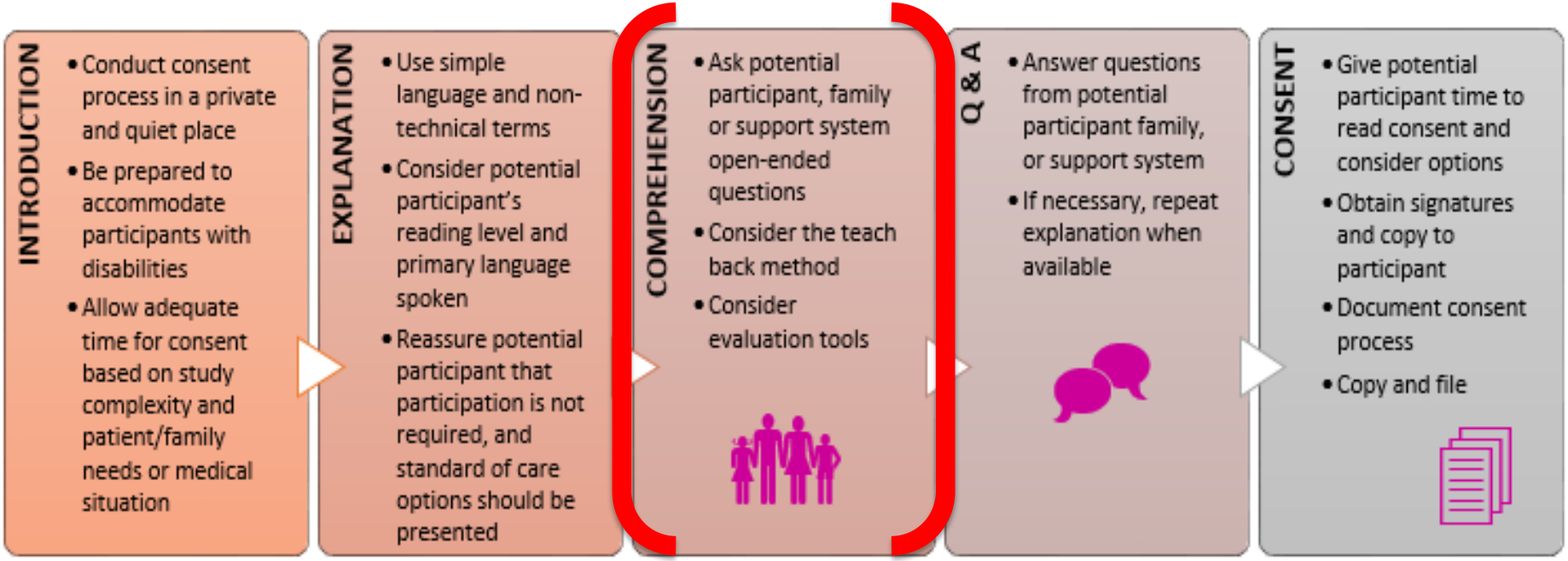
Practice: Plain Language

Medical/Research Terminology	Plain Language
Intervention	A treatment given in a study
Protocol	
Withdraw	
Enroll	
Adverse Event	
Efficacy	
Medication	

Plain Language Medical Dictionary *University of Michigan*

http://www.lib.umich.edu/plain-language-dictionary

Steps for Obtaining Informed Consent



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Comprehension

- Verify and document subject's understanding of the study and their responsibilities.

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What is Teach Back

- Communication strategy that confirms patient understanding in a non-shaming way
- Research based health literacy intervention
- Asking patients to explain, in their own words, what they need to know and/or do
- ***Not*** a test or a quiz
- Chunk and Check Information
- Person providing the information/education takes responsibility
- In our clinic we will be using the universal approach to health literacy

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Teach-Back Method

- Patients explain health information i
  words.

Yen, P. H., & Leasure, A. R. (2019). Use and Effectiveness of the Teach-Back Method in Patient Education and Health Outcomes. *Federal practitioner : for the health care professionals of the VA, DoD, and PHS*, *36*(6), 284–289.

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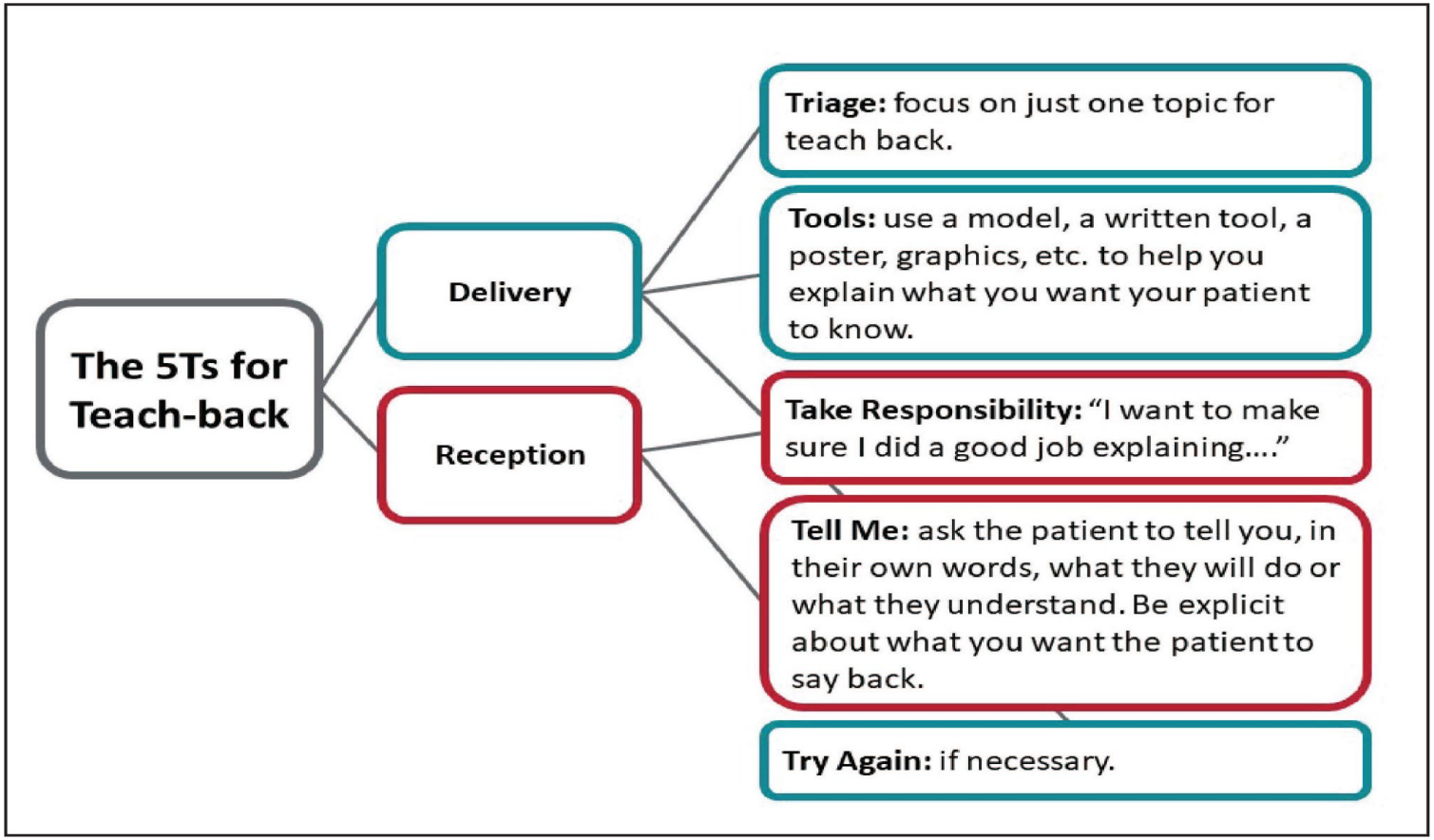
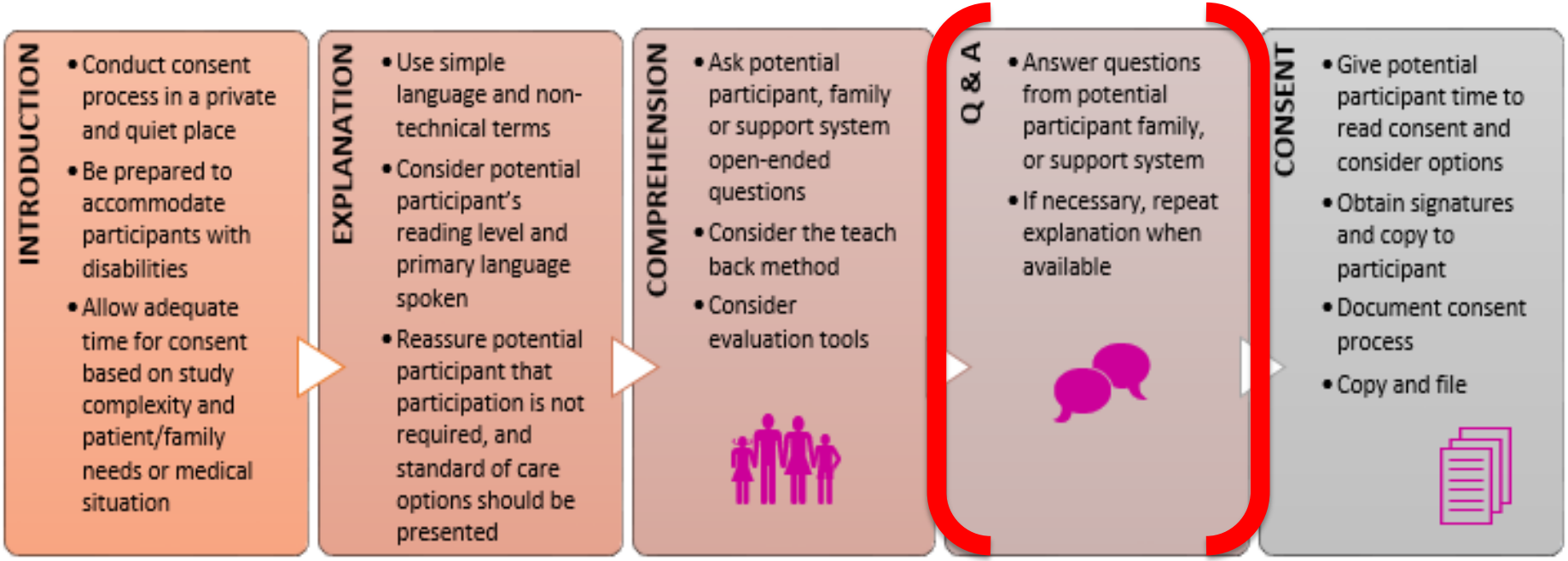


Anderson, KM et al. 2020

Take Responsibility

- Non-Shaming
- 2 elements
  - Acknowledge the complexity or amount of information
  - Imply that you are the person being tested, not the patient
  - Example: “I just gave you a lot of information and I want to make sure I did a good job explaining this to you”

Steps for Obtaining Informed Consent



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Questions and Answers

- Open-ended questions
  - "What questions do you have for me?"
  - "What would you like to hear more about?"
- Repeat Information as necessary
- Provide ample opportunity for Q&A

Methods and Considerations

RECONSENT

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Reconsent

- Research subjects be informed of any significant new findings identified during the course of the research which may impact the subject's willingness to continue participation.

[45 CFR 46.116(b)(5); 21 CFR 50.25(b)(5); ICH E6 4.8.2]

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Reconsenting

- Notify the IRB of minor or significant changes
- What process will be used to inform subjects of change
- IRB will review proposal and approve or require modification
- Attach all materials needed for re-consent

Reconsent Process

- Whether the new information is related to risks to or safety of the subjects;
- Whether the new information is a significant change from what was previously disclosed or explained to subjects;
- Whether the new information may impact a subject's willingness to continue with study participation; and
- Whether the subjects are still active in the study or have completed their participation.

Examples of Changes

- Significant
  - Additional risks or safety information were identified
  - Extend duration of study participation
  - Additional study visits or activities
  - Additional samples collection etc;
  - Drug dosing or schedule has significantly
  - PI change
- Minor
  - Study previously required 5cc of blood but now requires 10cc of blood
  - Changes to surveys unless new questions pose new risks

Considerations for reconsenting

Who? • Subjects actively undergoing research intervention • All subjects • Subset of subjects	• Does the change affect subjects differently? • If yes, clearly define each subset affected differently by the change (i.e. males, females, specific age groups, subjects in active treatment, specific study arm, subjects off study, etc.)
What? • Additional risks or change in risk severity or frequency • Change in level of discomfort or other inconvenience • Procedural changes including remuneration or reimbursement • New alternative options available	• Could the change affect a subjects decision to remain in the study? • Regulatory, ethical or policy requirements • New research findings • Will the change involve a different level of commitment from the subject?

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Considerations for reconsenting

When? • Immediate • Before next study visit • Before specific study procedures • Within specified time period • Varies with affected participant subset • Alternate plan if revised consent version not yet available when needed for subject	• Are subjects coming in for visits or are study procedures done at home? • Are subjects impacted now or in the future? • Are subjects who have completed study procedures/visits impacted? • Logistics (including any travel, expense or inconvenience to subjects)
Where and how? • Phone • Letter • Letter with phone follow-up • Revised consent form • In-person visit	• Complexity and need for interactive explanation and discussion • Need for physical demonstration or other presentation of information • Timeline for next subject visit • Verification of subject identity if not consented in person • Any subject limitations such as age, disabilities, language, vulnerable population

Methods for Reconsenting

- Consent Form Addendum
- Consent with a Revised Full Document
- Letter
- Telephone call

Considerations for Determining Methods of Notification

Participant Affected by Changes	Participant Not Affected by Changes
Study Participant Still Active in Study	
Examples: • New risk or increase risk of drug • New risk or increased risk of procedure subject will undergo • Changes to remuneration / reimbursement	Examples: • New procedure that the subject will not undergo (such as at baseline) • Arm/treatment not affected by change or risk (on a different treatment) • Subgroup not affected (women only- pregnancy testing)
Method of Notification: • Re-consent • If next study visit is greater than 30 days, notify via phone or letter, reconsent at next in-person visit	Method of Notification: • Typically, no notification needed

Adapted from the Mayo clinic

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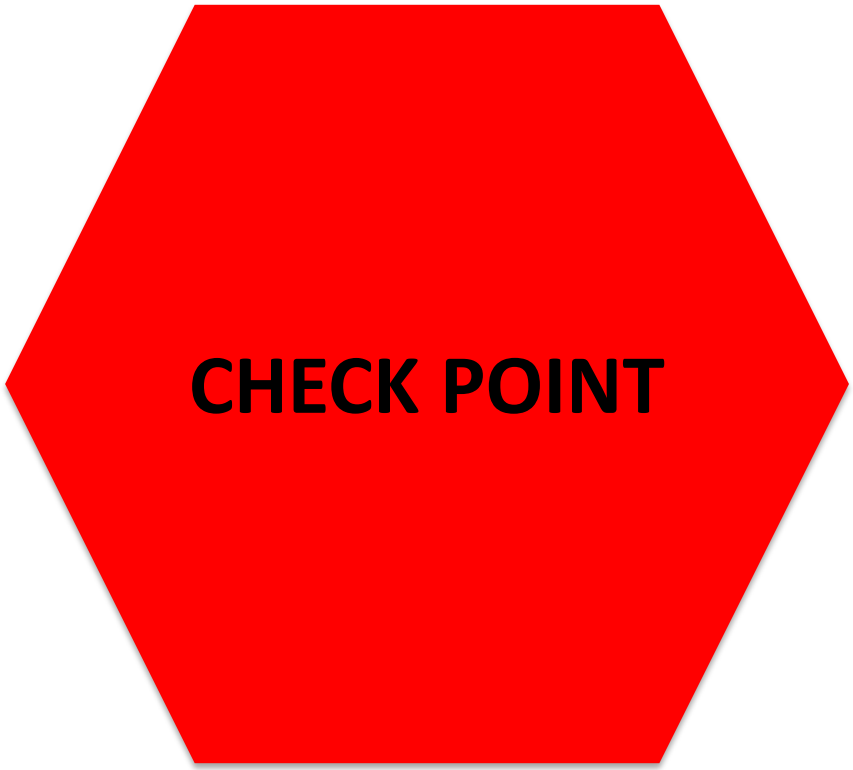
Considerations for Determining Methods of Notification	
Participant Affected by Changes	Participant Not Affected by Changes
Study Participant has Completed Procedures and All Study Visits	
Examples: • Newly identified long-term or late-occurring risk	Examples: • Changes to procedure or protocol • Newly identified immediate, short-lasting risk
Method of Notification: • Letter to notify of potential long-term or late-occurring risk • Phone	Method of Notification: • Typically, no notification needed

Adapted from the Mayo Clinic



TRUE or FALSE

All changes to the study procedures or risks require a modification to the full informed consent and re-consenting participants face to face.

Questions?

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