Considerations for modernizing the informed consent process

Nichelle Cobb, Association for the Accreditation of Human Research Protection Programs

Christine Suver, Sage Bionetworks

Objectives

Discuss challenges with informed consent

Illustrate key design principles to enhance readability that were followed to improve an informed consent process for an Alzheimer's Disease Research Center study

Explore barriers to improving informed consent and how research teams and IRBs might overcome the

Informed consent is one of the ways we insure that research ethics are applied in research studies

Photo by Cytonn Photography on Unsplash

Common problems with the informed consent process and forms

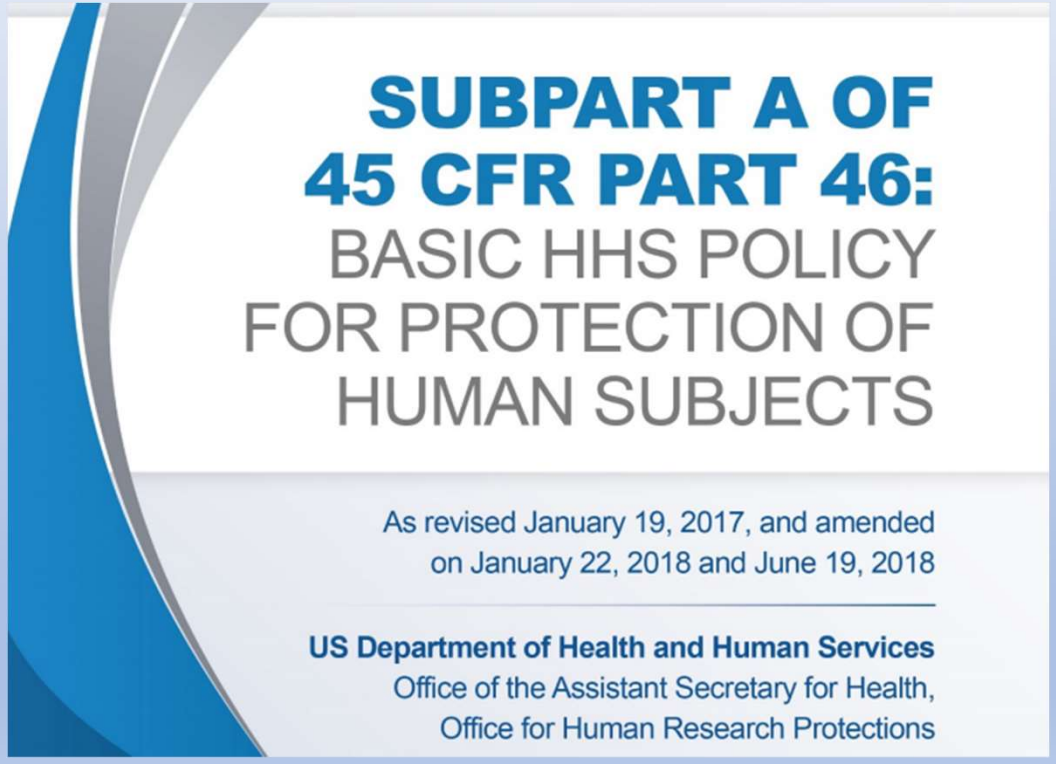
Excessive length

Technical language

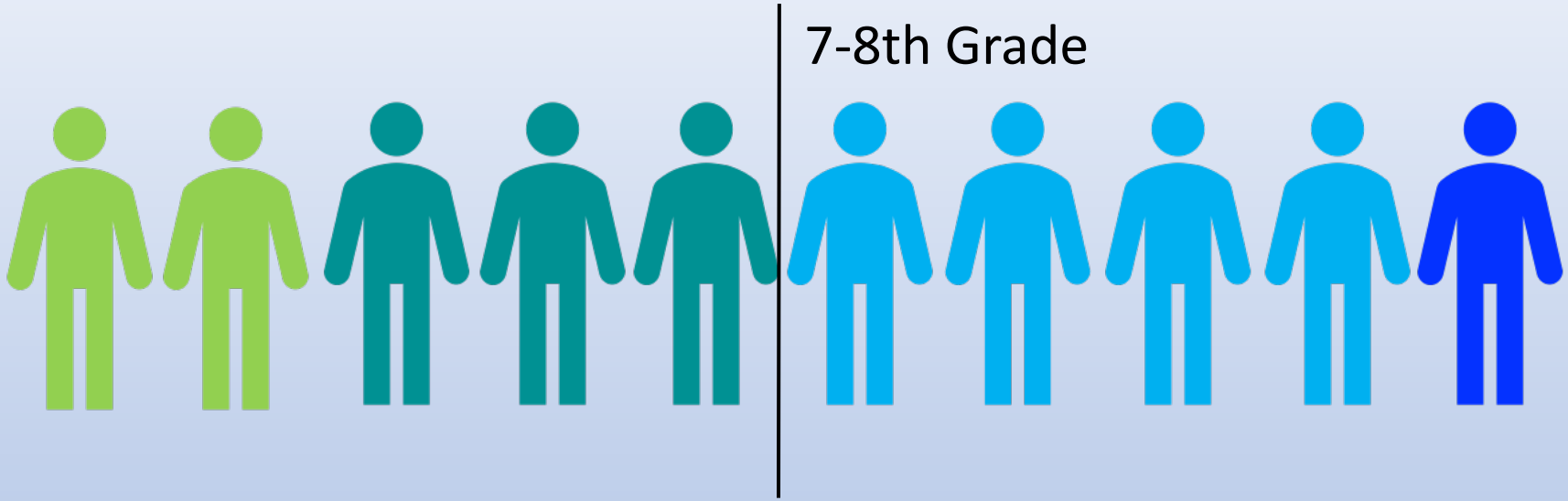
Forms are more of a legal document meant to protect institutions rather than providing information that participants need to decide whether or not to join a study

Trying to address the problem: Revised Common Rule requirements

The 2018 version of the Common Rule (and potential the FDA regulations in future) obligates IRBs to ensure the informed process facilitates comprehension and includes information that a reasonable person would want to have in order to make an informed decision about whether to participate



Literacy in the US



1 in 2 American adults reads at a basic or below-basic level

~ 18% Below Basic
~ 34% Basic
~ 36% Proficient
~ 12% Highly Proficient

PIAAC: Program for the International Assessment of Adult Competencies (2012-2017)

Gallup analysis

Improving Comprehension

Components of Literacy and Readability

The reader's proficiency in the language that information is presented in

Number of words and length of document

Language complexity

Reading ease

How information is presented

https://consenttools.org/optimizing-key-information/

- **§46.116 General Requirements for Informed Consent. (a)(3)** The information that is given to the subject or the legally authorized representative shall be **in language understandable to the subject or the legally authorized representative.**

- This means:
  - The language someone can speak or read proficiently (e.g., English, Portuguese, Swahili, Esperanto),
  - Reading level, and
  - Ease of reading, comprehension, evaluation, and utilization of information

Informed consent - Language

Choose common words	Avoid jargon	Define technical terms	Short sentences (no more than 15-20 words)
Keep paragraphs short – 1 idea per paragraph	Avoid using acronyms and abbreviations	Use the same terms consistently	Use active voice (who is supposed to do what)

https://consenttools.org/optimizing-key-information/

Readability Analysis

From the great resource by Meg Doerr, Sage Bionetworks: A Quick Primer on Readability
http://sagebionetworks.org/wp-content/uploads/2018/11/Primer-on-readability-25April17-1.pdf

Aim for the lowest reading grade level possible to get the greatest number of people to be able to read it

- Flesch-Kincaid 5th grade reading level is readable by ~80% of the US public
- Flesch-Kincaid 8th grade reading level is readable by ~50% of the US public
- Flesch-Kincaid 12th grade reading level is readable by ~10% of the US public

Aim for a high reading ease

- Flesch reading ease of 70.0 and above is a minimum goal. 80.0 and above is better.
- Flesch reading ease of 50.0 and below is readable by college students, 30.0 and below by college graduates.

Assessment of Length and Readability of Informed Consent Documents for COVID-19 Vaccine Trials

Ezekiel J. Emanuel, MD, PhD; Connor W. Boyle, BA

- The language complexity in all the documents exceeded a grade 9 reading level, which is higher than the recommended grade 6 reading level
- All the documents had scores of less than 60 in the reading ease metric, with a mean (range) score of 52.4 (49.6-56.8), categorizing them as difficult
- Adults with slower reading ability (175 wpm) would require a mean (range) of 47.6 (44.7-53.4) minutes, if they were able to read without stopping

Table 1. Characteristics of the Phase III COVID-19 Vaccine Randomized Clinical Trial Informed Consent Documents[a]

Metric	Pfizer	Johnson & Johnson	Moderna	AstraZeneca	Mean	Proposed alternative
Length, pages, No.	25	25	20	17	21.8	10
Document reading time, min						
175 wpm (lower bound)	44.7	47.7	53.4	44.7	47.6	16.9
240 wpm (mean)	32.6	34.8	38.9	32.6	34.7	12.3
300 wpm (upper bound)	26.1	27.8	31.1	26.1	27.8	9.9
Word count, No.						
Whole document	7828	8341	9340	7821	8333	2960
Risk section	884	989	1445	977	1074	200
Privacy section	2478	1955	1280	1750	1866	778
Reading grade level						
Whole document	9.8	8.8	9.6	11.3	9.9	7.6
Risks section	9.5	8.5	9.4	11.2	9.7	6.1
Privacy section	11.7	10.7	11.5	13.1	11.8	9.6
Reading ease[b]						
Whole document	52.2	56.8	51.1	49.6	52.4	61.8
Risks section	58.8	56.8	54.8	46.9	54.3	71.2
Privacy section	39.8	48.7	40.3	41.0	42.5	53.8

Abbreviation: wpm, words per minute.

[a] Range, 0 to 100, with 100 indicating easiest to read and scores less than 60 considered difficult by the Department of Health and Human Services.

JAMA Network Open. 2021;4(4):e2110843. doi:10.1001/jamanetworkopen.2021.10843 April 28, 2021 2/5

Readability is important, but what else do we need to do to make informed consent better?

What else promotes informed consent?

Knowledge check with corrected feedback

Interpersonal relationships with study teams

Electronic format

No one technique is consistently better, rather a combination of these and other elements appears to improve the informed consent process

References:

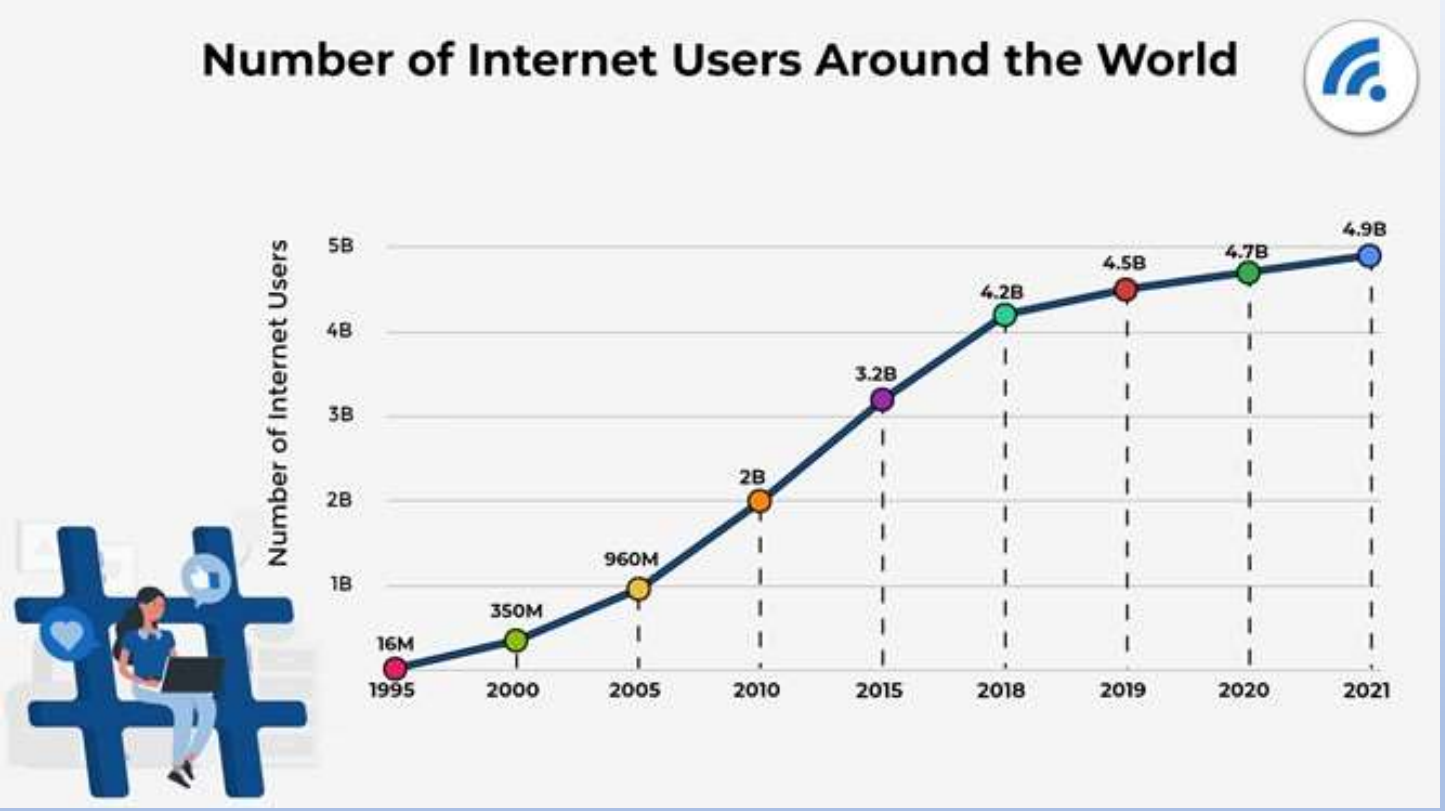
- **Flory & Emmanuel 2004**
- **Nishimura et al 2013**

Informed consent - Formatting

- Font size at least 12 point or larger
- Be mindful of fonts used?
- Use white space (margin sizes at least 1 inch)
- Use headings
- Avoid dense text
- Bullet points
- Incorporate graphics and other visual aids

https://consenttools.org/optimizing-key-information/

Why Format Matters



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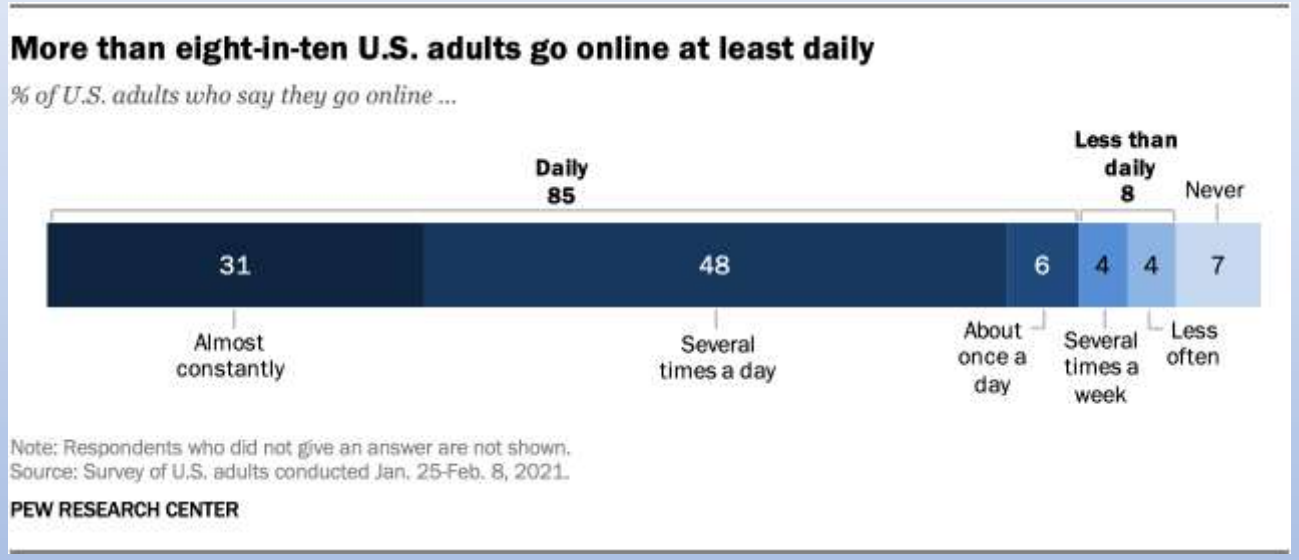

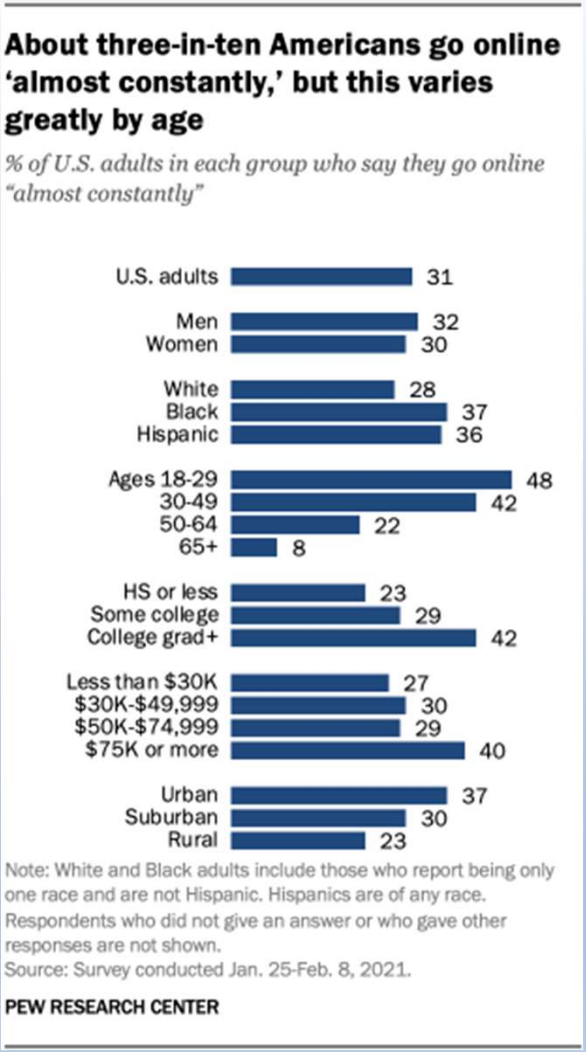

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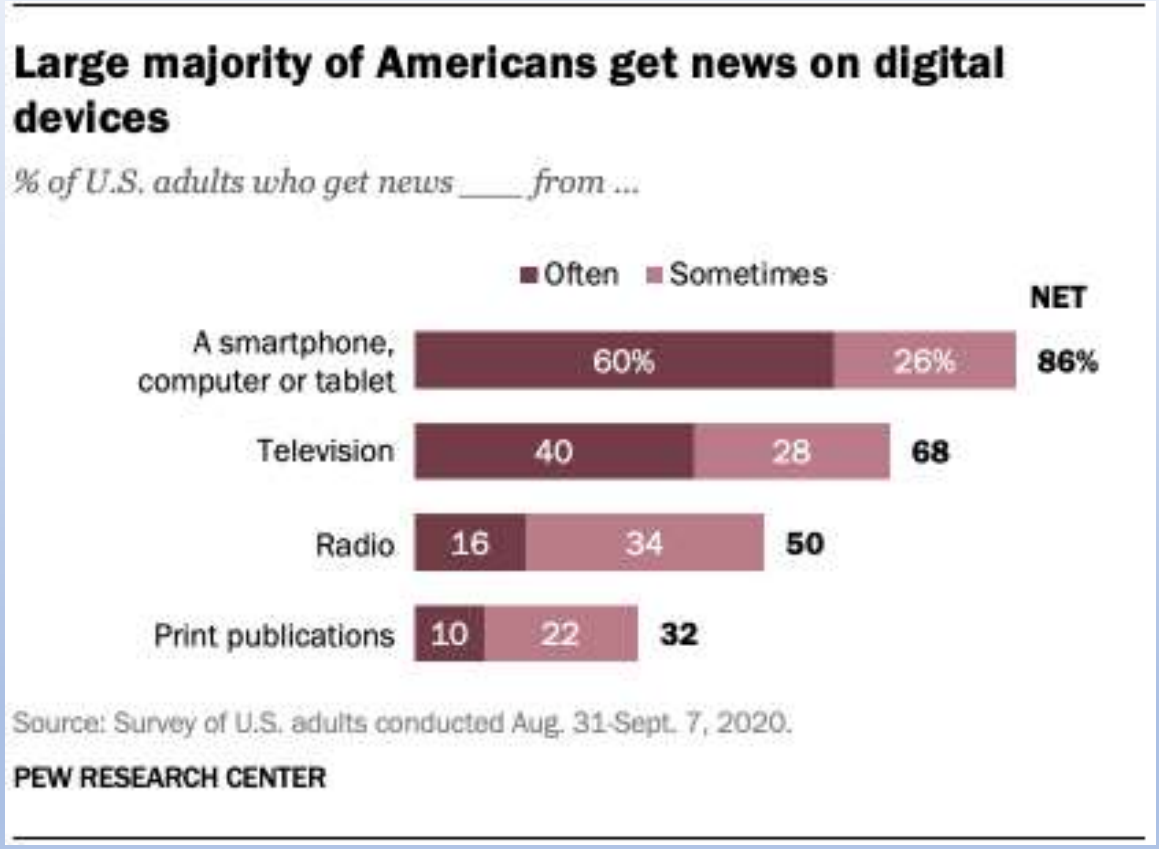
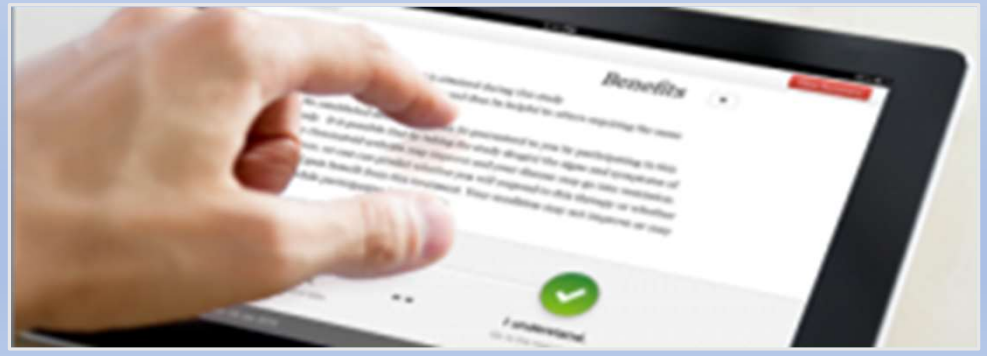
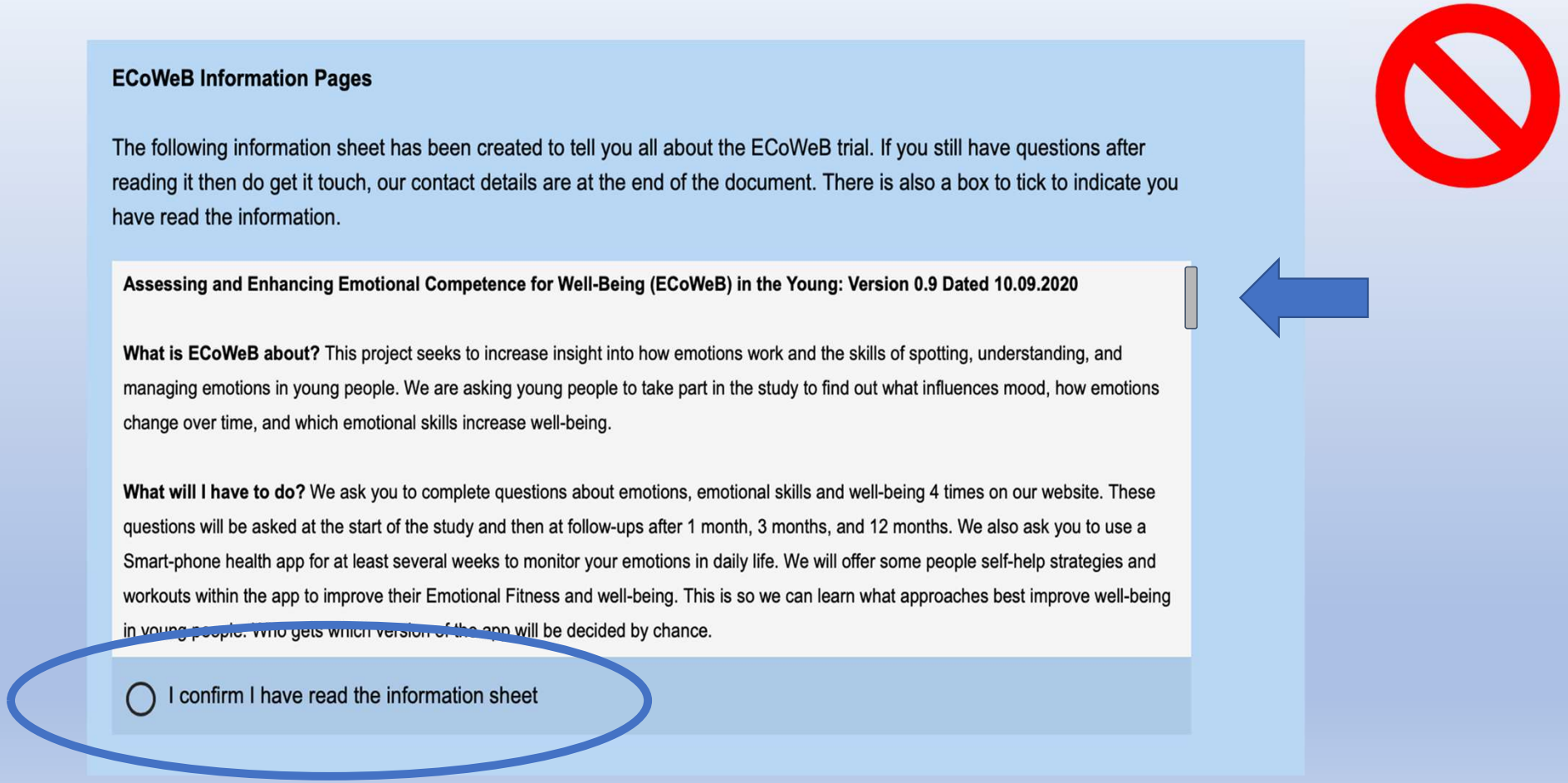


https://www.pewresearch.org/fact-tank/2021/01/12/more-than-eight-in-ten-americans-get-news-from-digital-devices/

Reimagining the informed consent process



Different ways to structure an eConsent



ECoWeB Information Pages

The following information sheet has been created to tell you all about the ECoWeB trial. If you still have questions after reading it then do get it touch, our contact details are at the end of the document. There is also a box to tick to indicate you have read the information.

Assessing and Enhancing Emotional Competence for Well-Being (ECoWeB) in the Young: Version 0.9 Dated 10.09.2020

What is ECoWeB about? This project seeks to increase insight into how emotions work and the skills of spotting, understanding, and managing emotions in young people. We are asking young people to take part in the study to find out what influences mood, how emotions change over time, and which emotional skills increase well-being.

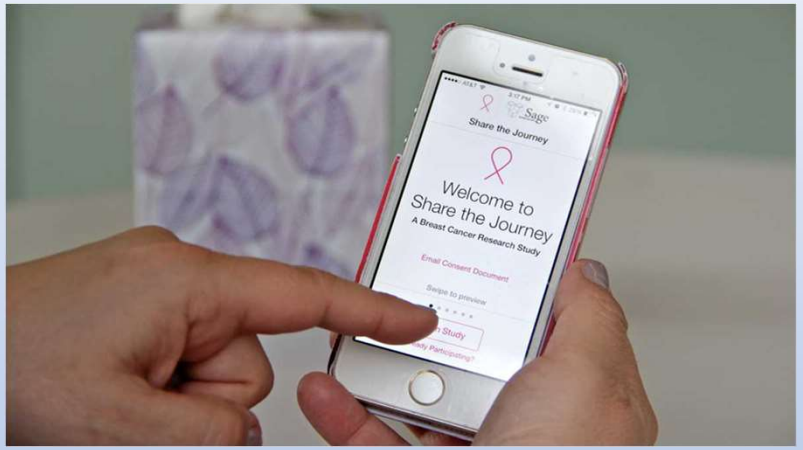
What will I have to do? We ask you to complete questions about emotions, emotional skills and well-being 4 times on our website. These questions will be asked at the start of the study and then at follow-ups after 1 month, 3 months, and 12 months. We also ask you to use a Smart-phone health app for at least several weeks to monitor your emotions in daily life. We will offer some people self-help strategies and workouts within the app to improve their Emotional Fitness and well-being. This is so we can learn what approaches best improve well-being in young people. Who gets which version of the app will be decided by chance.

I confirm I have read the information sheet

sagebionetworks.org/in-the-news/elements-informed-consent/

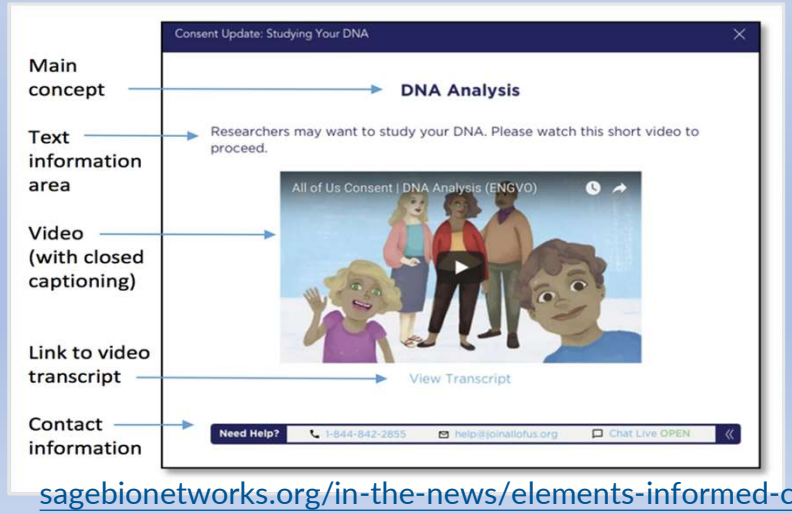
Different ways to structure an eConsent

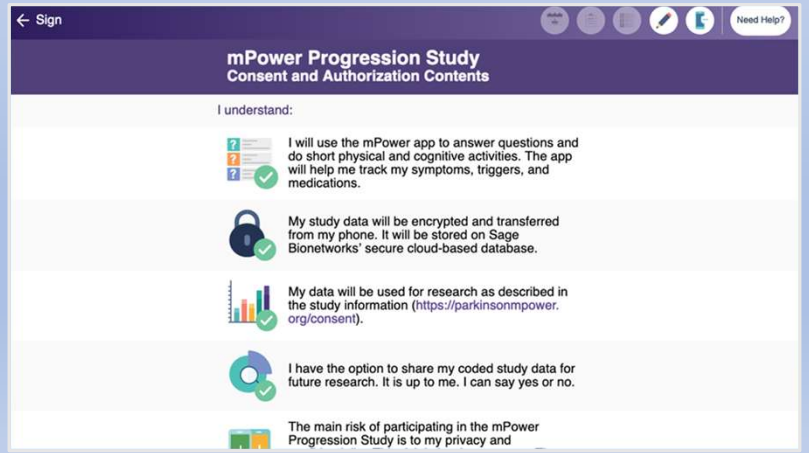
Better



Tapping

Videos





Icons

sagebionetworks.org/in-the-news/elements-informed-consent/

Developing an Interactive eConsent Process for Two Alzheimer's Disease Research Centers

Example of an interactive consent tool two Alzheimer's Disease Research Center study teams developed with Sage Bionetworks

Wisconsin Alzheimer's Disease Research Center
UNIVERSITY OF WISCONSIN
SCHOOL OF MEDICINE AND PUBLIC HEALTH

Dorothy Farrar-Edwards
Hannah Blazel
Erin Chin
Nichelle Cobb
Ken Croes
Carey Gleason
Sanjay Asthana

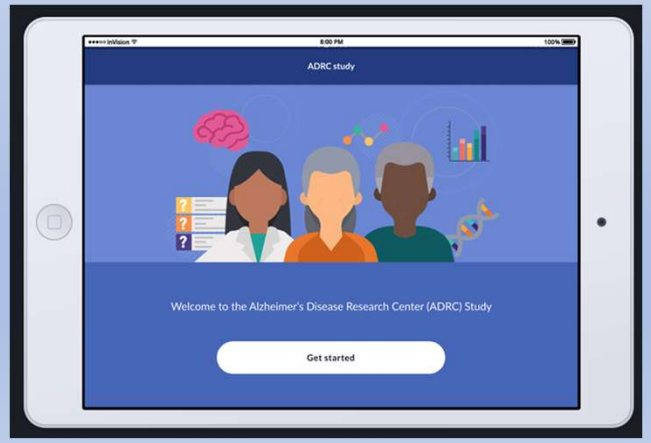
EMORY UNIVERSITY

Jim Lah
Cecelia Manzanares
Felicia Goldstein
Allan Levey

SageBionetworks

Christine Suver
Brian Bot
Allie Seroussi
Woody McDuffy
Stockard Simon
Amy Tran
Jennifer Hamann
Meg Doerr
John Wilbanks
Lara Mangravite

ADRC Study coordinators, Research Participants and partners

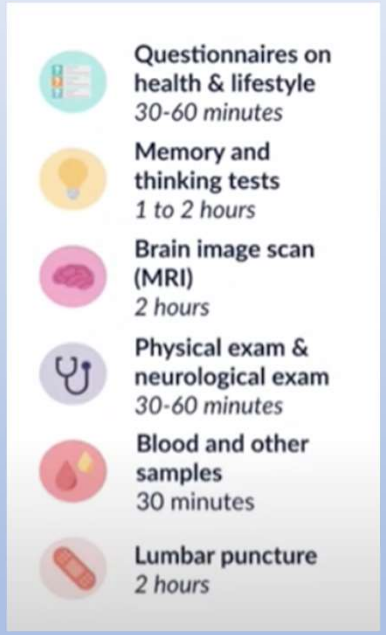


Alzheimer’s Disease research

Longitudinal
– Partners - Researchers

2018
2019
2020
2021
2022
2023
2024
2025

invasive procedures



Patients

No symptoms → Mild Cognitive Impairment (MCI) → Alzheimer’s Disease

Project goals

Create a participant-centered process that:

- **Builds trust**
- **Facilitates comprehension of the research**
- **Adapts to a population with memory deficit**
- **Supplement the interaction with the study coordinator/team**
- **Enhances the discussion with the study coordinator/team**

Stakeholder engagement

Study participants, partners, study coordinators, researchers, designers and IRB

- Barriers and facilitators of consent to AD research
- Integrate the revised Common Rule requirements
- Re-assess information / language
- Test early eConsent designs

REFLECT → ITERATE → REFINE

REPEAT

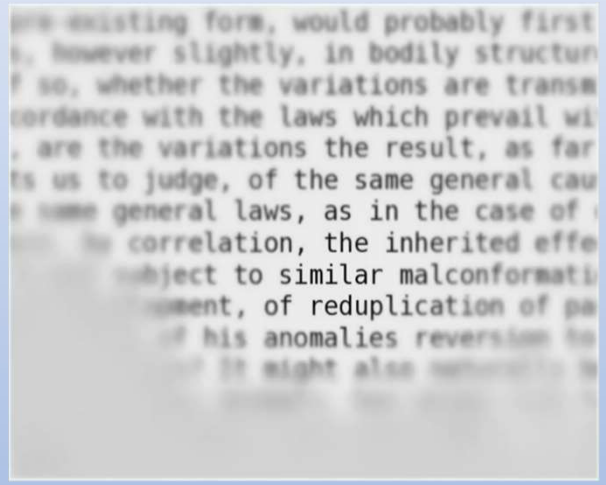
* Suver et al (2020) :10.1080/23294515.2020.1737982

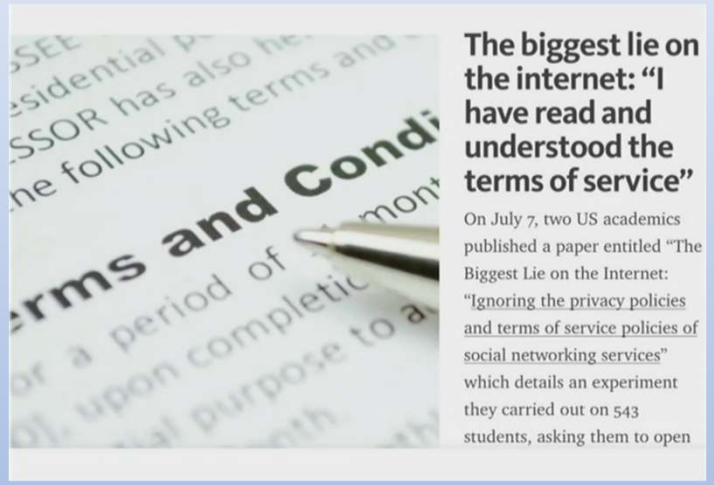
Design principles

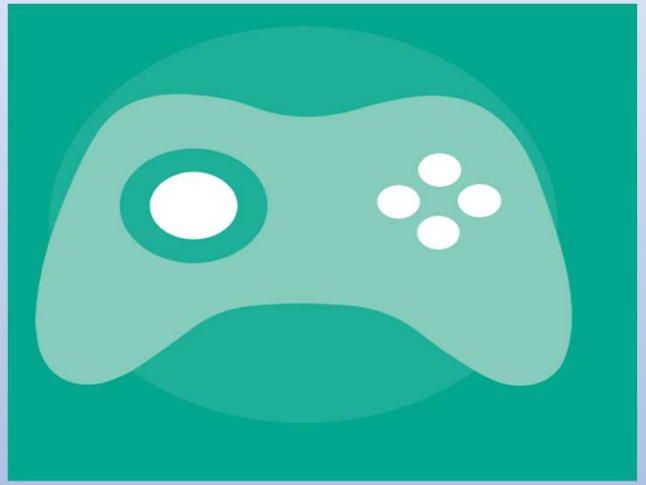
Design with intent to slow down,

provoke thought, and learn

Ethical Design Considerations

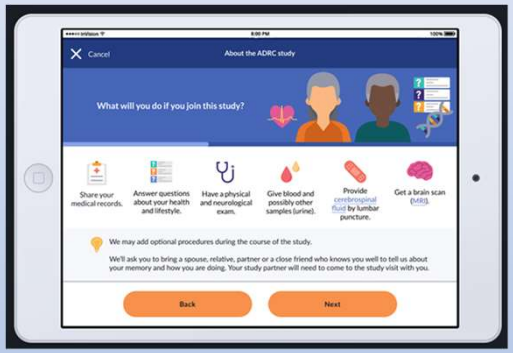







INTERACTIVE
IMPROVE COMPREHENSION
LINKS TO EXPLORE
SELF ASSESSMENTS
EASY TO UPDATE
LESS PRESSURE
MORE CONTROL

ADRC eConsent Elements

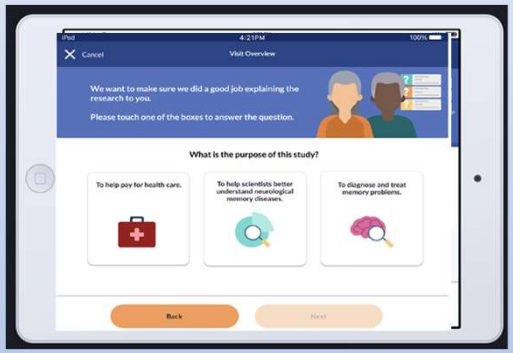


Introduction screens

Informed consent must begin with a concise & focused presentation of why someone would or wouldn't want to take part in the study

Information screens "narrative" TOC

Informed consent must provide information that a reasonable person would want to have to make a decision



Comprehension Quiz

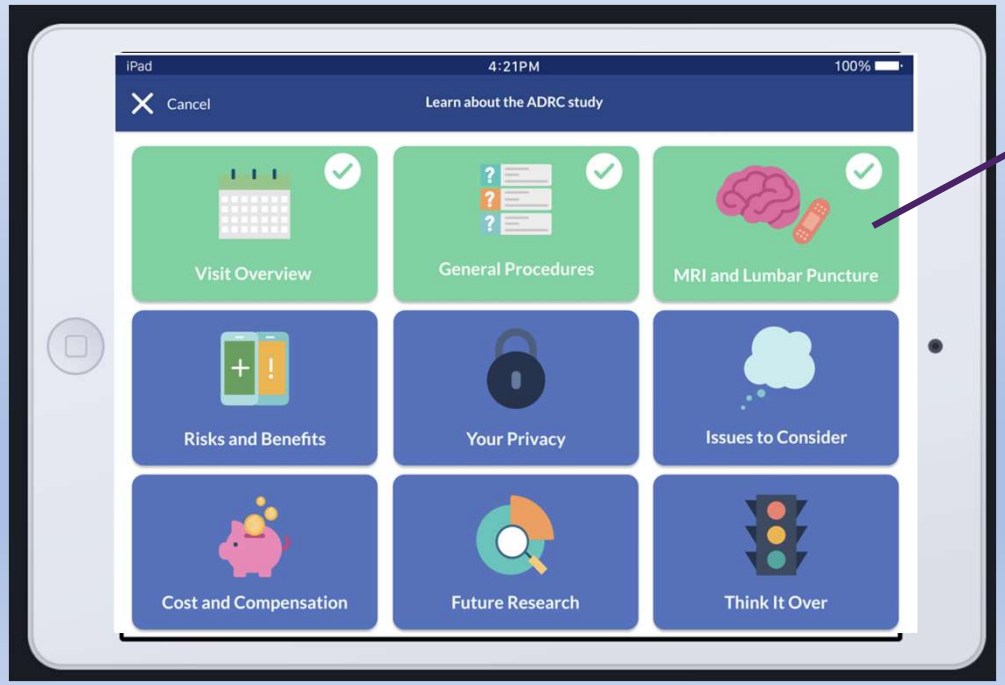
Informed consent should facilitate comprehension

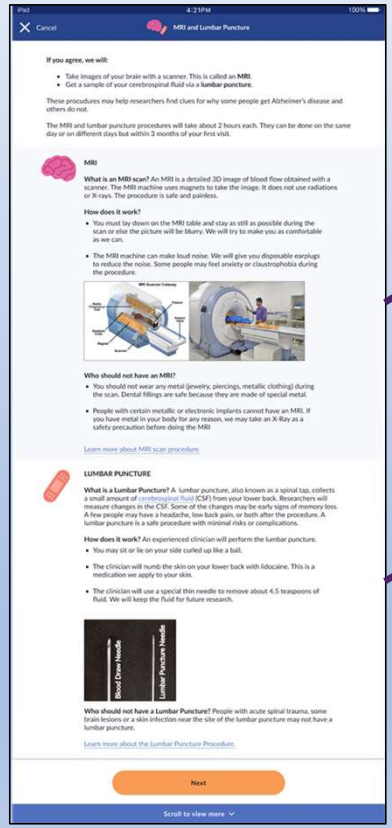
Review & Signature

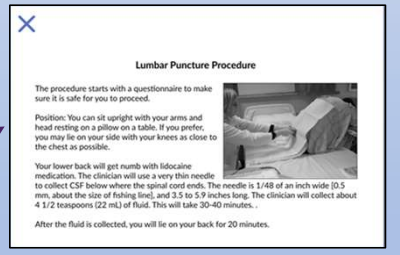
Informed consent must be documented (unless waived by an IRB)

eConsent Narrative - Self-guided exploration

Modules are presented after the concise and focused summary screens

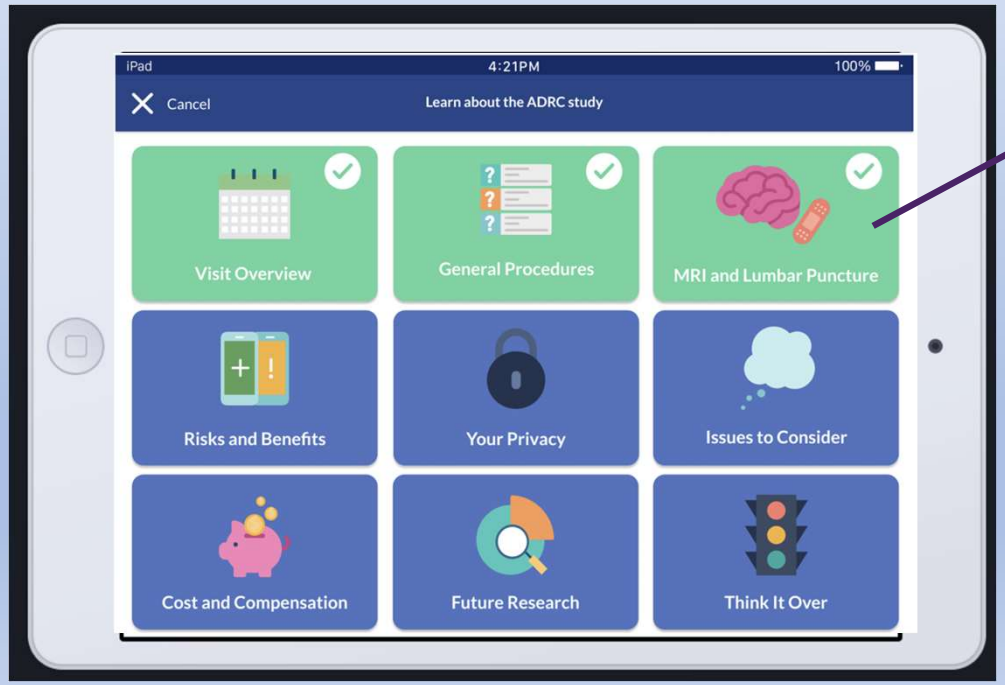


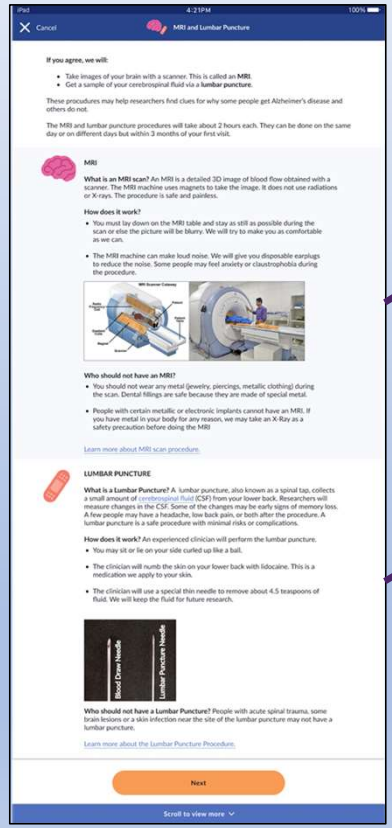


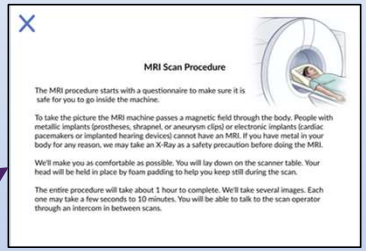


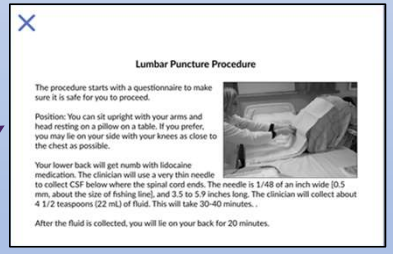
The tool was developed to display on a tablet and sections of the informed consent were divided into modules that allowed participants to access information in their preferred order

Each section included pictures and icons plus pop up windows that provided additional information if desired



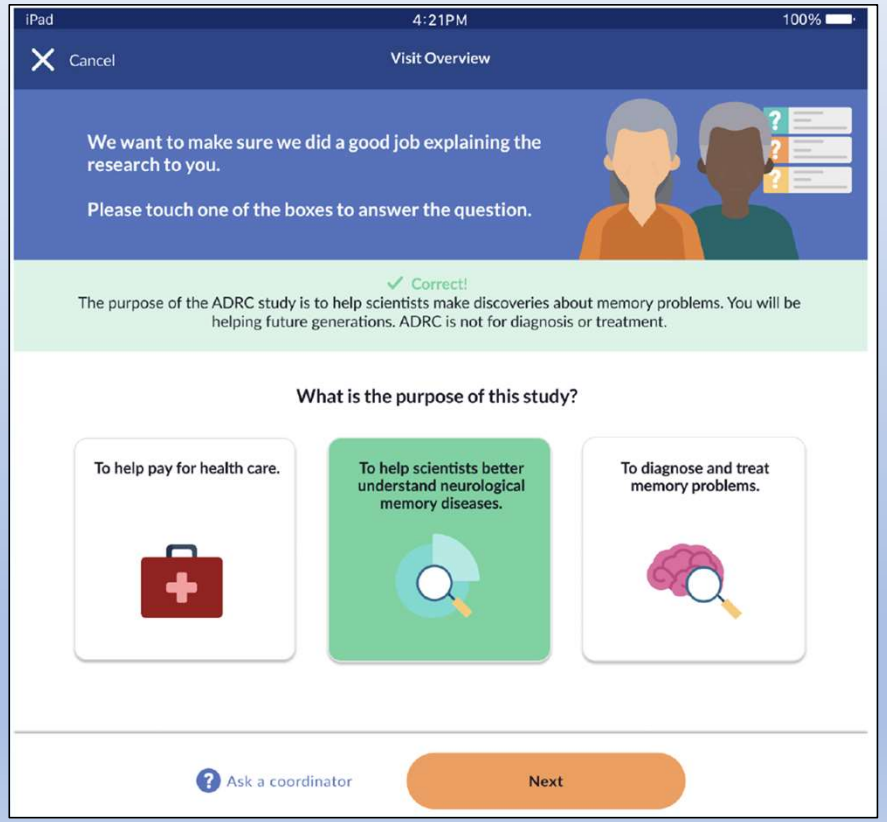


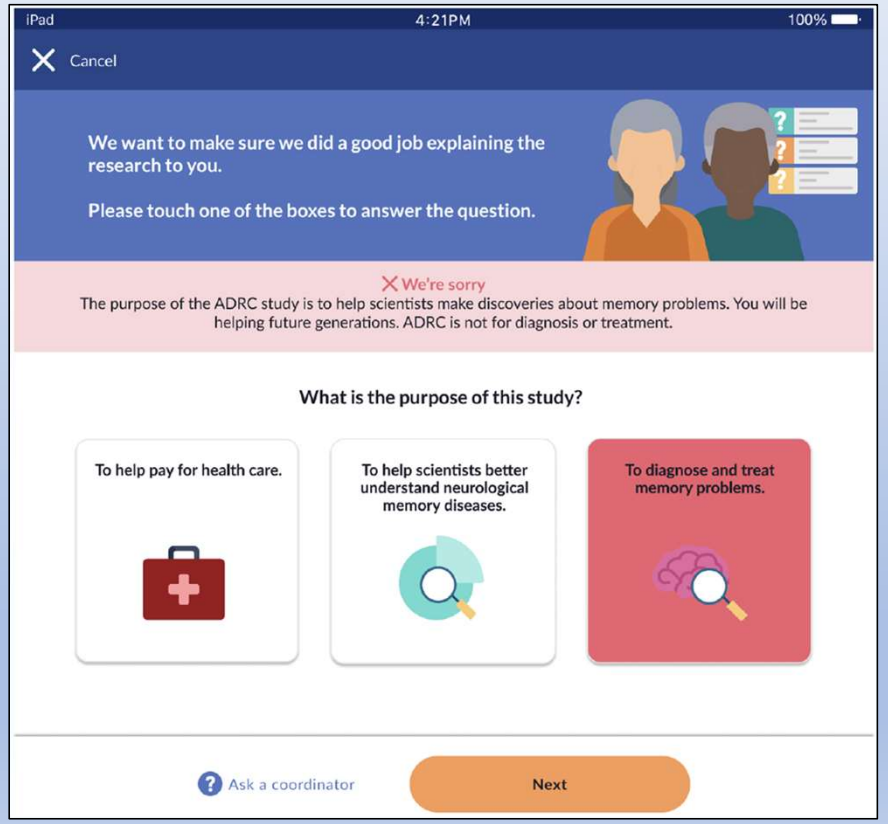




Including a knowledge check

Key questions were presented at the end of each module to check participants' understanding and provide feedback to them. Coordinators could follow up on areas that suggested an incomplete understanding



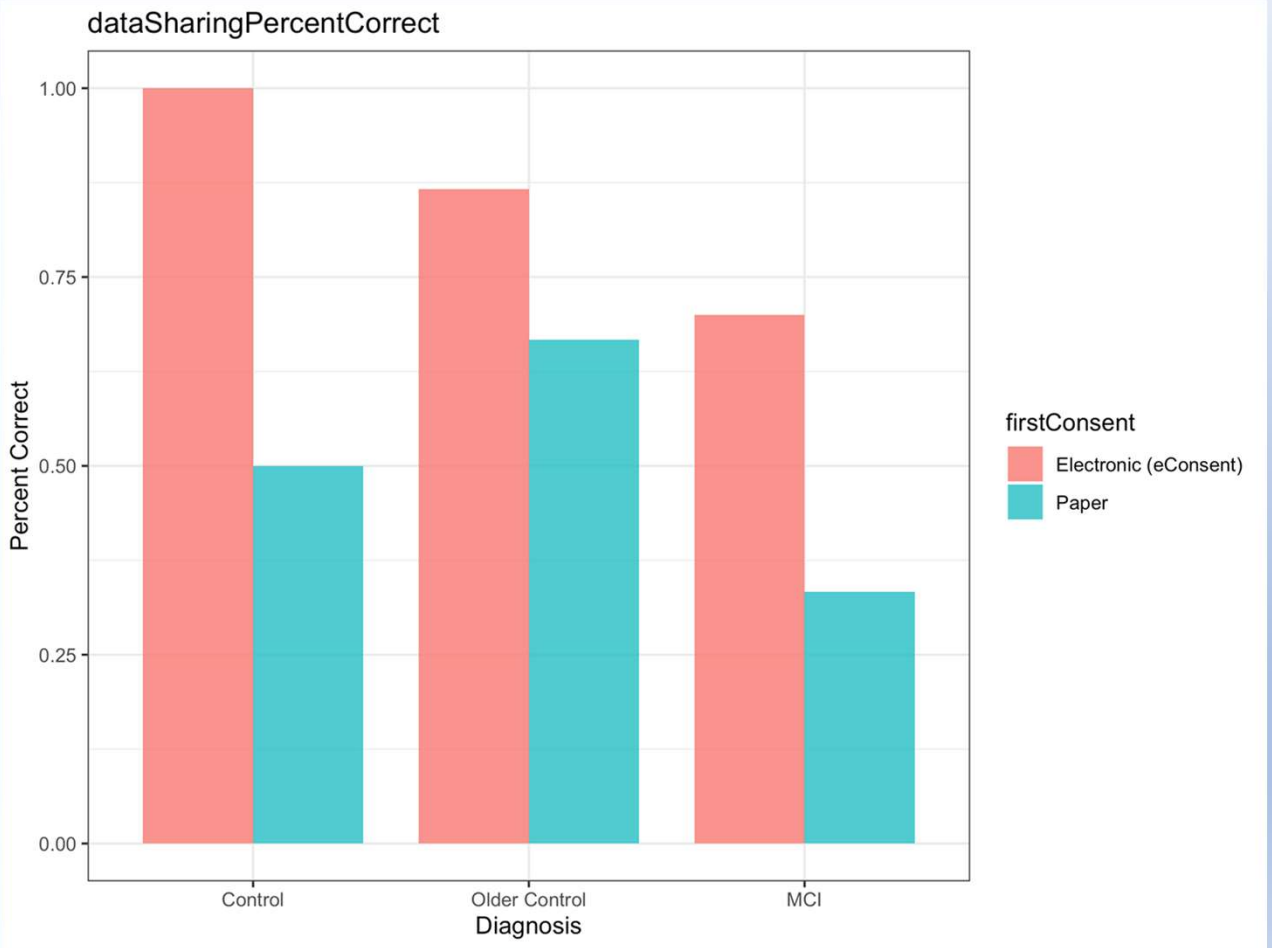


Does eConsent Work?

Comprehension questions

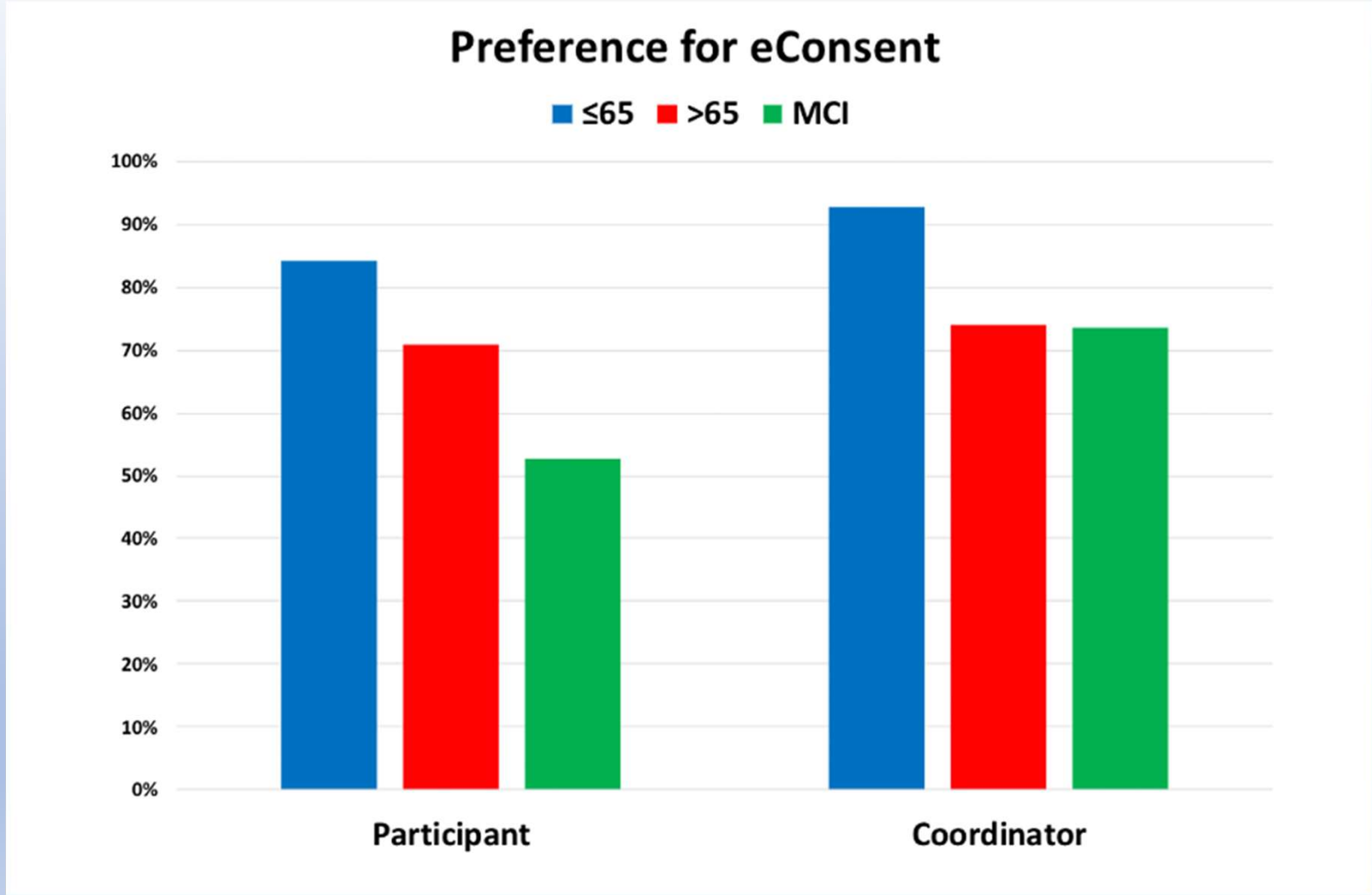
- Visit Overview: What is the purpose of this study?
- General Procedures: What general procedure is not part of this study?
- MRI and Lumbar Puncture: Which statement is true?
- Risks and benefits: Are there risks to participating in the ADRC study?
- Risks and benefits: Are there risks of having a brain scan (MRI)?
- Privacy: How will my privacy be protected?
- Results: What results will I get?
- Costs and Compensation: Will I receive a bill for study procedures?
- Future Research: How long will your samples be stored?
- Think it Over: Do I have to take part in the research study?

Comprehension – 1 of 10 questions



Which one of the following best describes who will have access to your study samples and data?

a. … any researcher who asks for them
b. … no one outside the study team
c. … my personal physician only
d. … qualified researchers outside our institution for other research studies


Preference for eConsent
≤65
>65
MCI
100%
90%
80%
70%
60%
50%
40%
30%
20%
10%
0%
Participant
Coordinator

Why participants like the eConsent

Controls

MCI

I prefer reading to listening

I was able to set my own pace

move through more swiftly with enhanced understanding

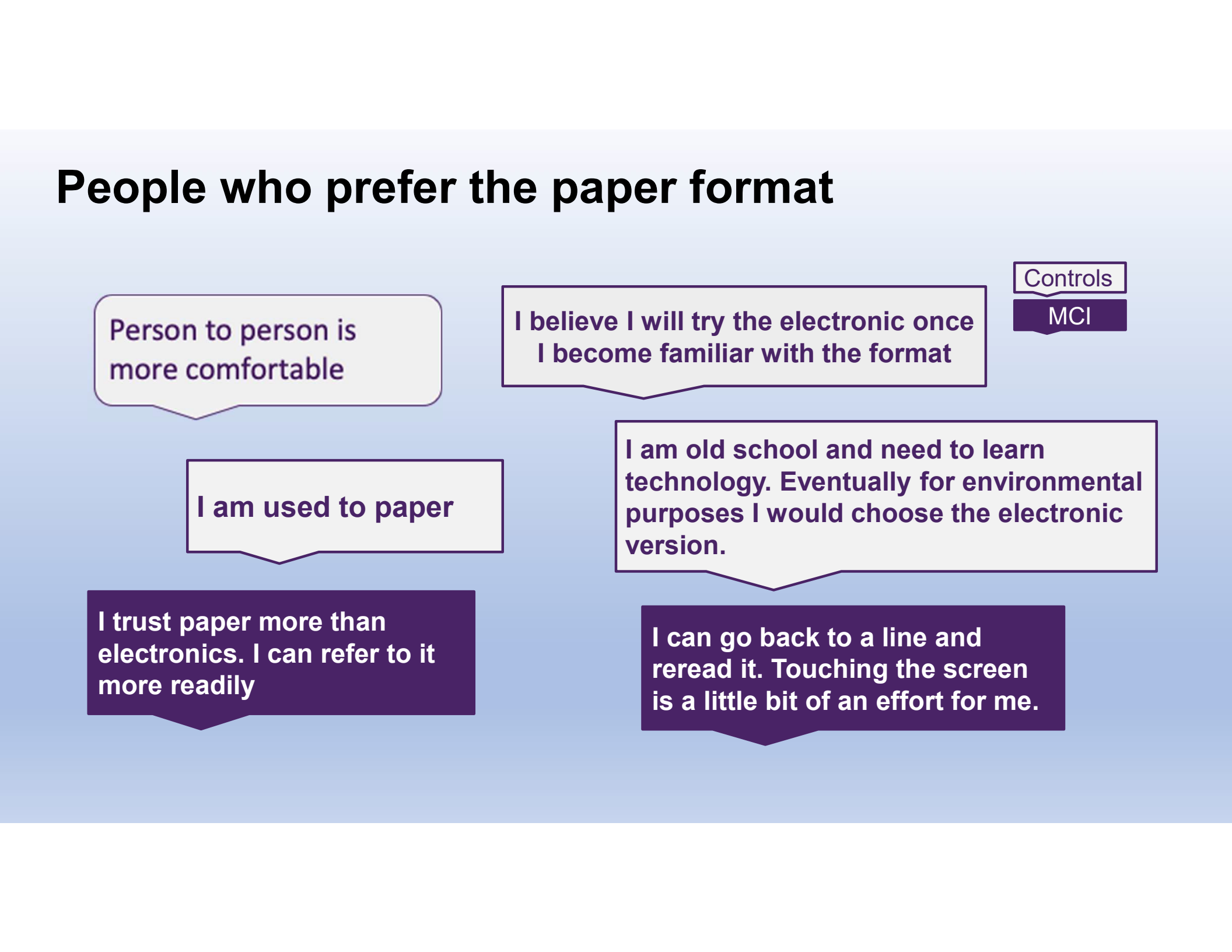
Easier to read

I could go at my own speed and concentrate on the issue that I was reading

Colorful, kept my attention better

Better, included reviews

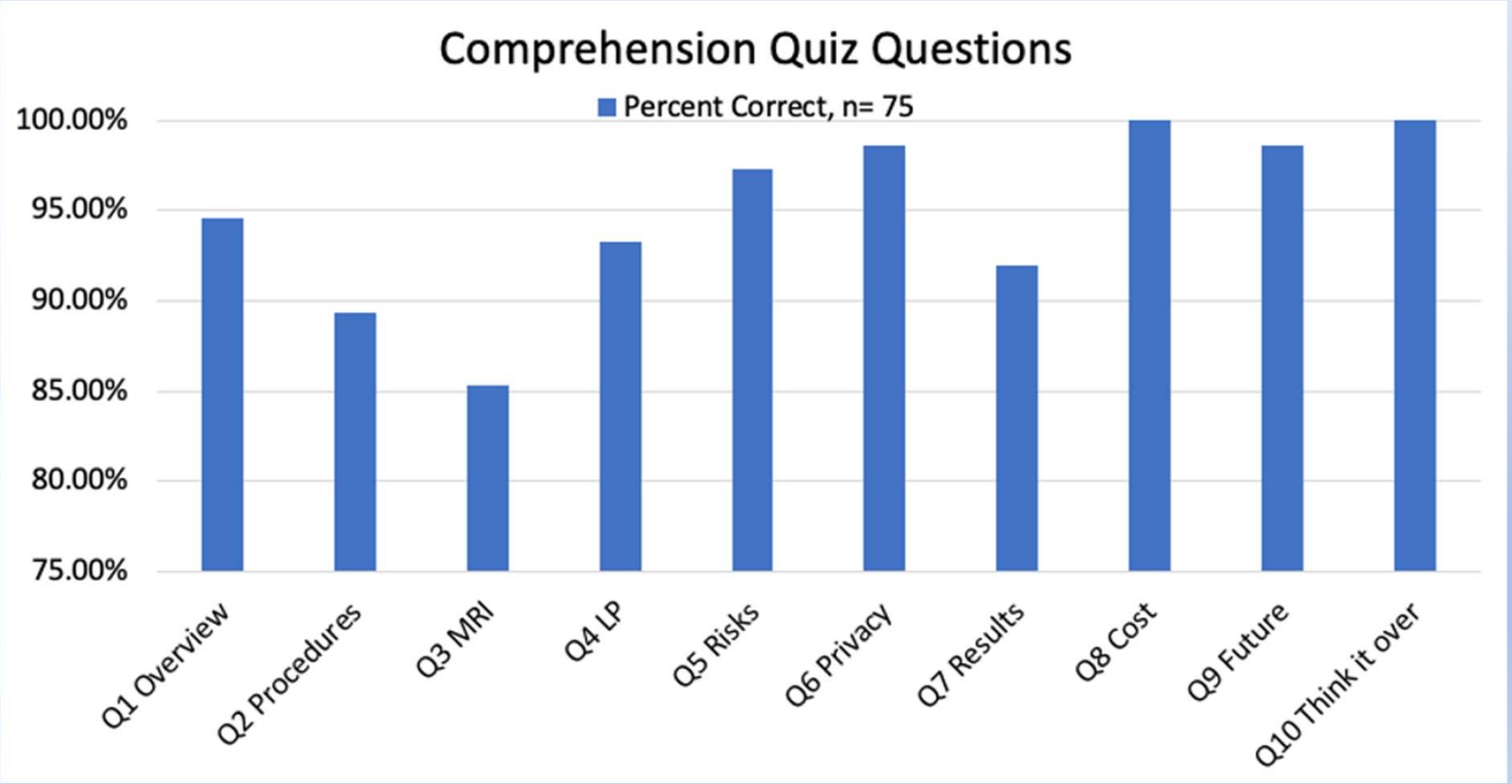
People who prefer the paper format



Implementation in REDCap

- Study participants received a unique code sent via email directly from REDCap to complete the eConsent.
- Participants could choose to complete the eConsent on their own or be guided through the eConsent with a study coordinator.
- Study coordinators were able to view the completed eConsent and score the quiz questions.
- Study coordinators were asked to review all incorrect quiz questions with the study participant.

The 10 quiz questions were answered correctly by most participants from both centers



If we know what improves informed consent, why are we not applying best practices?

Source Documents

Sponsors (industry and federal) often do not provide template documents that meet readability standards

eConsent

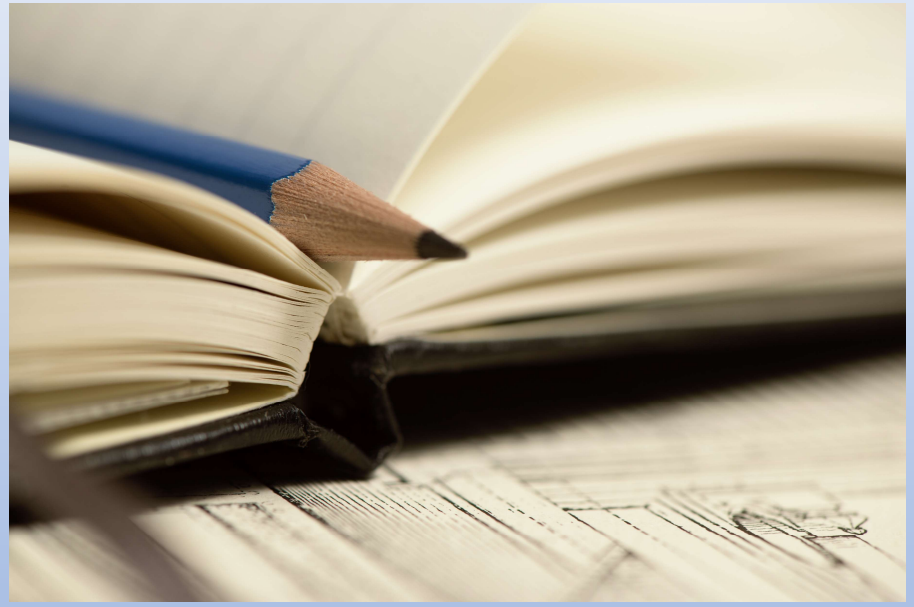
The possibilities that an electronic format have to offer are not always leveraged

When used, the electronic informed consent document rarely differs from a paper presentation of the information

Expertise

Informed consent documents for investigator-initiated research are often not developed by individuals with expertise in literacy (especially health literacy)

Training on how to conduct an informed consent process is often not emphasized at organizations

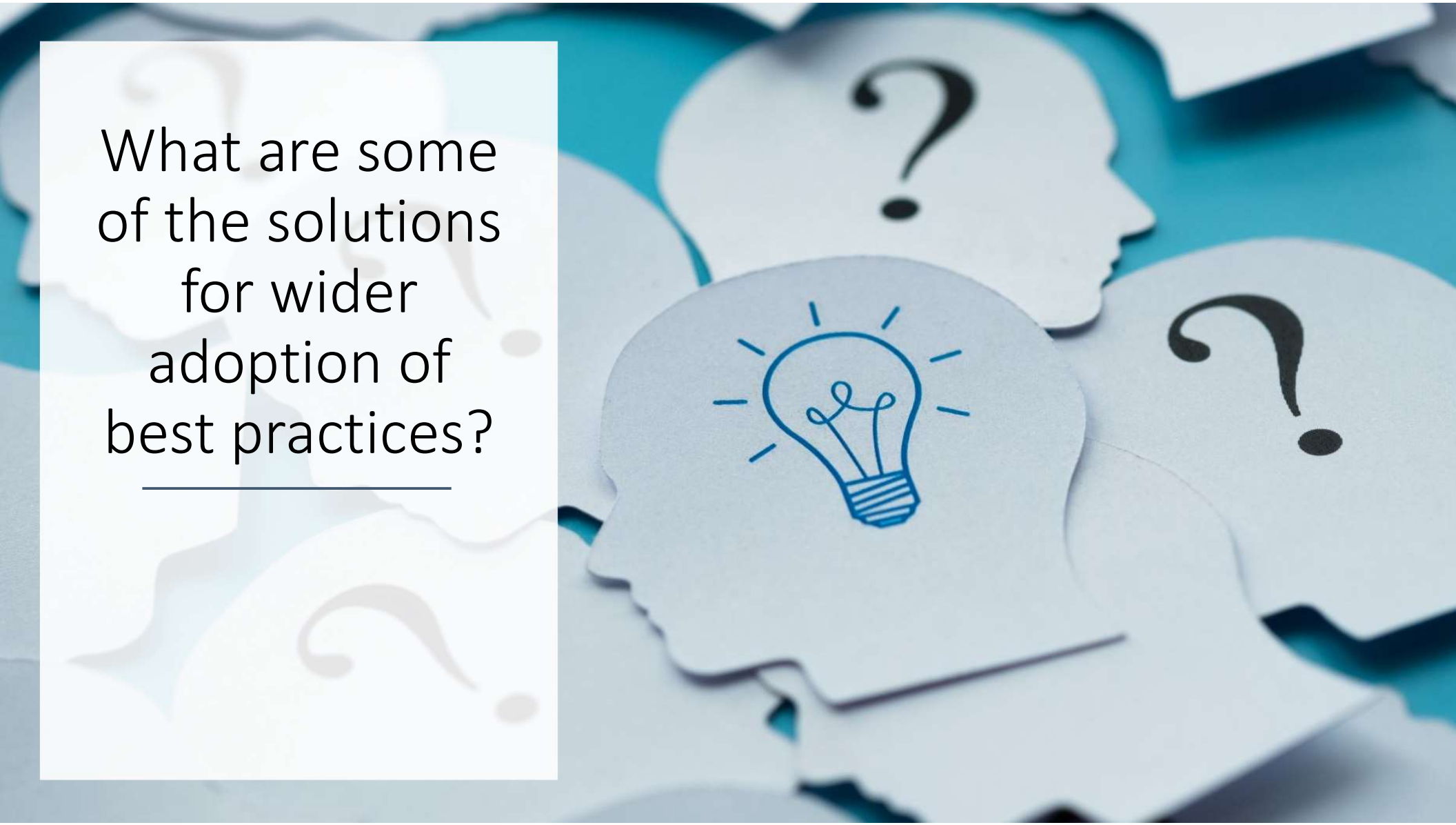


Time and resources

IRBs often do not have the bandwidth to edit to the degree needed to significantly improve readability nor do organizations have experts available to help create robust consent forms

Templates help but have their limits

What are some of the solutions for wider adoption of best practices?



Selected resources

- PRISM Readability Program (Toolkit + Online Training)
  - https://www.kpwashingtonresearch.org/about-us/capabilities/research-communications/prism
- MRCT: HEALTH LITERACY IN CLINICAL RESEARCH
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From paper to screen: regulatory and operational considerations for modernizing the informed consent process

Nichelle L. Cobb[1], Dorothy F. Edwards[2], Erin M. Chin[2], James J. Lah[3], Felicia C. Goldstein[3], Cecilia M. Manzanares[3] and Christine M. Suver[4]

[1]Association for the Accreditation of Human Research Protection Programs, Inc. (AAHRPP), Washington, DC, USA; [2]University of Wisconsin-Madison School of Medicine and Public Health, Wisconsin Alzheimer's Disease Research Center, Madison, WI, USA; [3]Emory University, Goizueta Alzheimer's Disease Research Center, Atlanta, GA, USA and [4]Sage Bionetworks, Seattle, WA, USA

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Author for correspondence:
C.M. Suver, PhD, Sage Bionetworks, 2901 Third Ave, Suite 330, Seattle, WA 98121, USA. Email: christine.suver@sagebase.org

Abstract

Electronic platforms provide an opportunity to improve the informed consent (IC) process by permitting elements shown to increase research participant understanding and satisfaction, such as graphics, self-pacing, meaningful engagement, and access to additional information on demand. However, including these elements can pose operational and regulatory challenges for study teams and institutional review boards (IRBs) responsible for the ethical conduct and oversight of research. We examined the experience of two study teams at Alzheimer's Disease Research Centers who chose to move from a paper-based IC process to an electronic informed consent (eIC) process to highlight some of these complexities and explore how IRBs and study teams can navigate them. Here, we identify the key regulations that should be considered when developing and using an eIC process as well as some of the operational considerations eIC presents related to IRB review and how they can be addressed.

Thank you!

Contact us!

- Nichelle Cobb, ncobb@aahrpp.org
- Christine Suver, christine.suver@sagebase.org