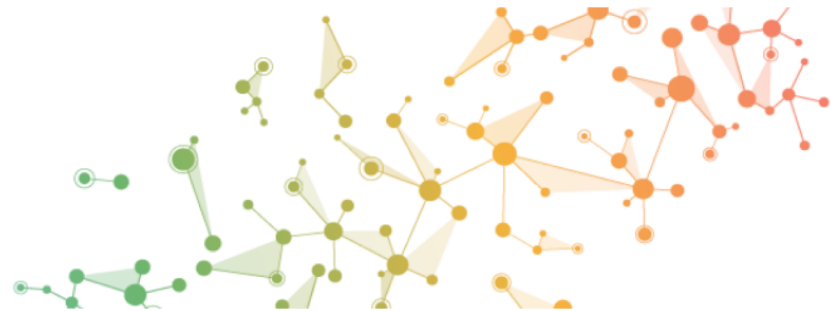


Participant-Centered Design for ADRC Informed Consent

Christine Suver
ADC-ORE- 19 Oct 2018

Better Science Together





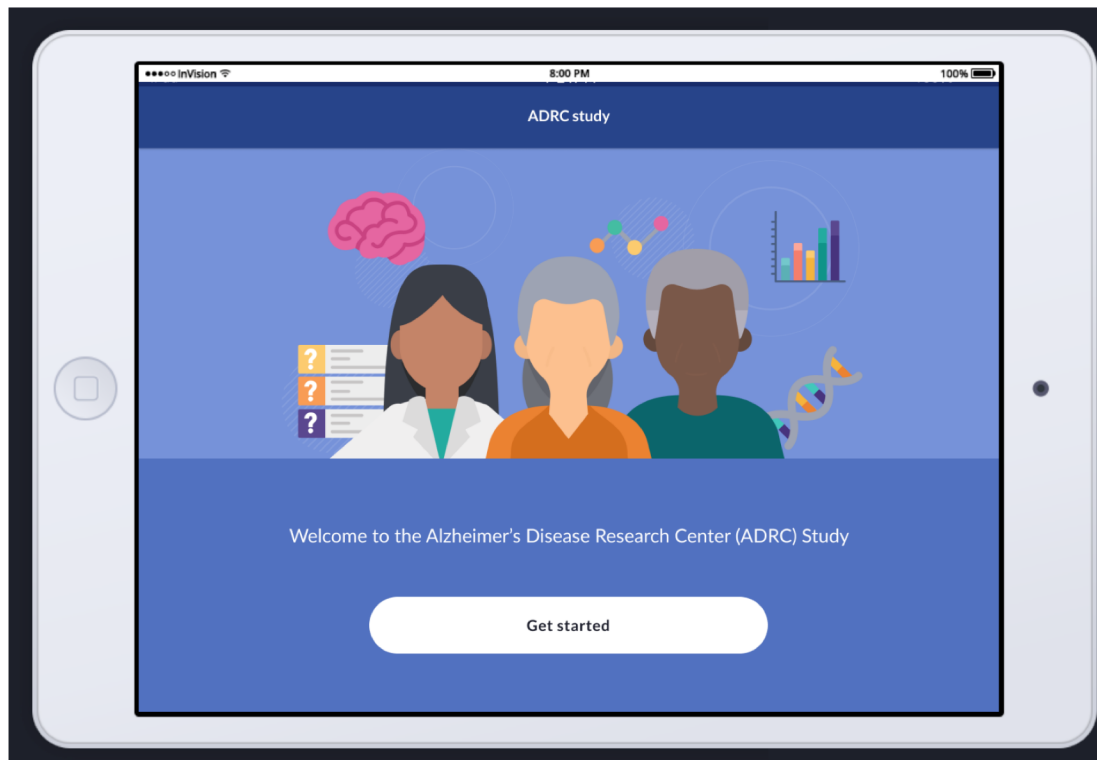
Dorothy Farrar-Edwards
Hannah Blazel
Erin Chin
Nichelle Cobb
Ken Croes



Jim Lah
Cecelia Manzanares
Felicia Golstein



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



ADRC Study coordinators
Volunteers

Barriers & Facilitators

- Interviews
 - Study coordinators
 - Participants w/ MCI- AD
 - IMPACT Participants
 - Partners



Qualitative analysis

Emerging themes

- Barriers:
 - The length of both the form and the process
 - Complex study procedure (biomarkers)
 - Expertise/ lack of confidence of the coordinator
 - Frustration about lack of access to data and test results (research vs. care)
- Facilitators
 - Add visual aids
 - Adapting the cadence and order of topics
- Coordinators recommendations:
 - Shortening the form/process
 - Clarify confusing areas i.e. study liability and information sharing procedures
 - Provide *optional* information for people who wish additional details



pre-existing form, would probably first
be, however slightly, in bodily structure
if so, whether the variations are transmissible
in accordance with the laws which prevail with
us, are the variations the result, as far
as we are able to judge, of the same general cause
and the same general laws, as in the case of
various other correlations, the inherited effects
of which are subject to similar malconformations
and, consequently, of reduplication of parts
of his anomalies reversion to
the normal. It might also naturally be
expected that the same laws would apply to the



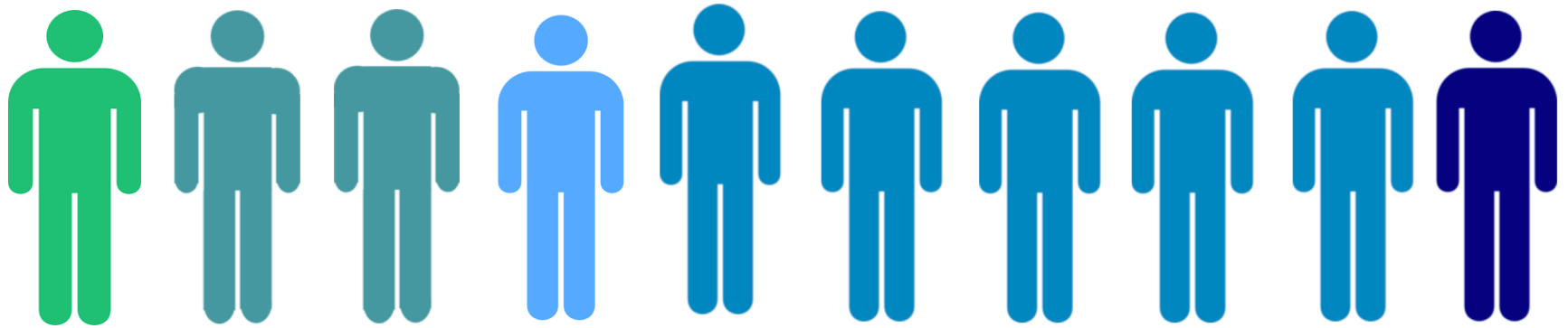
The biggest lie on the internet: “I have read and understood the terms of service”

On July 7, two US academics published a paper entitled “The Biggest Lie on the Internet: “Ignoring the privacy policies and terms of service policies of social networking services” which details an experiment they carried out on 543 students, asking them to open

The Candy Crush effect

“Make everything a game. Make it interactive and fun. Even though kids are the ones supposed to be playing games to learn, it makes it easier for adults too. It also makes it fun and makes me want to come back to finish the task every day...”

Reading and Health literacy



1 in 3 American adults reads at a basic or or below basic level

14% Below basic

21% Basic

53% Intermediate

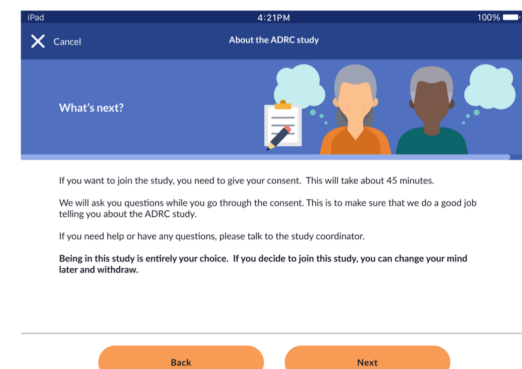
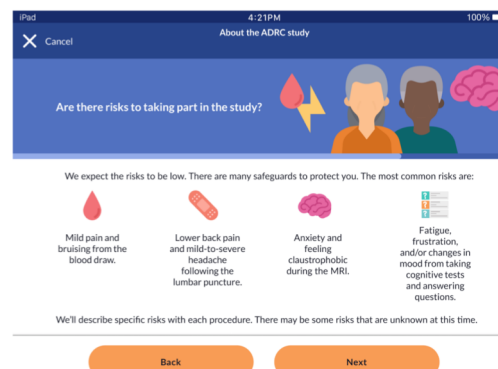
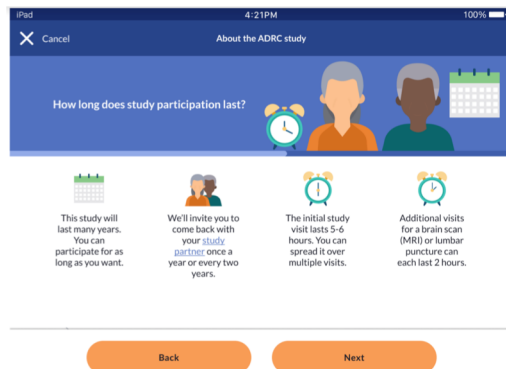
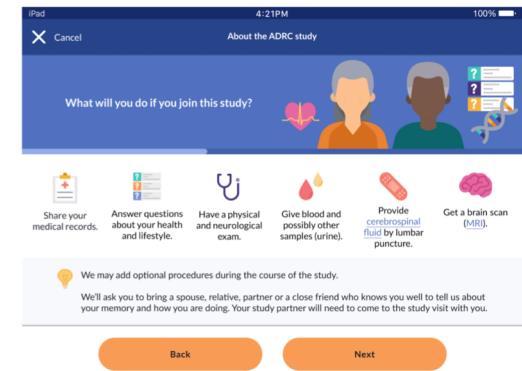
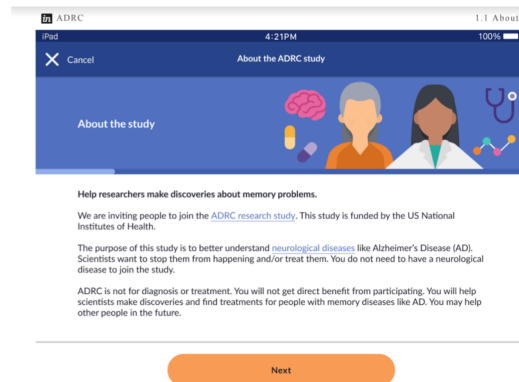
12% Proficient

Revised Common Rule- effective Jan 2019

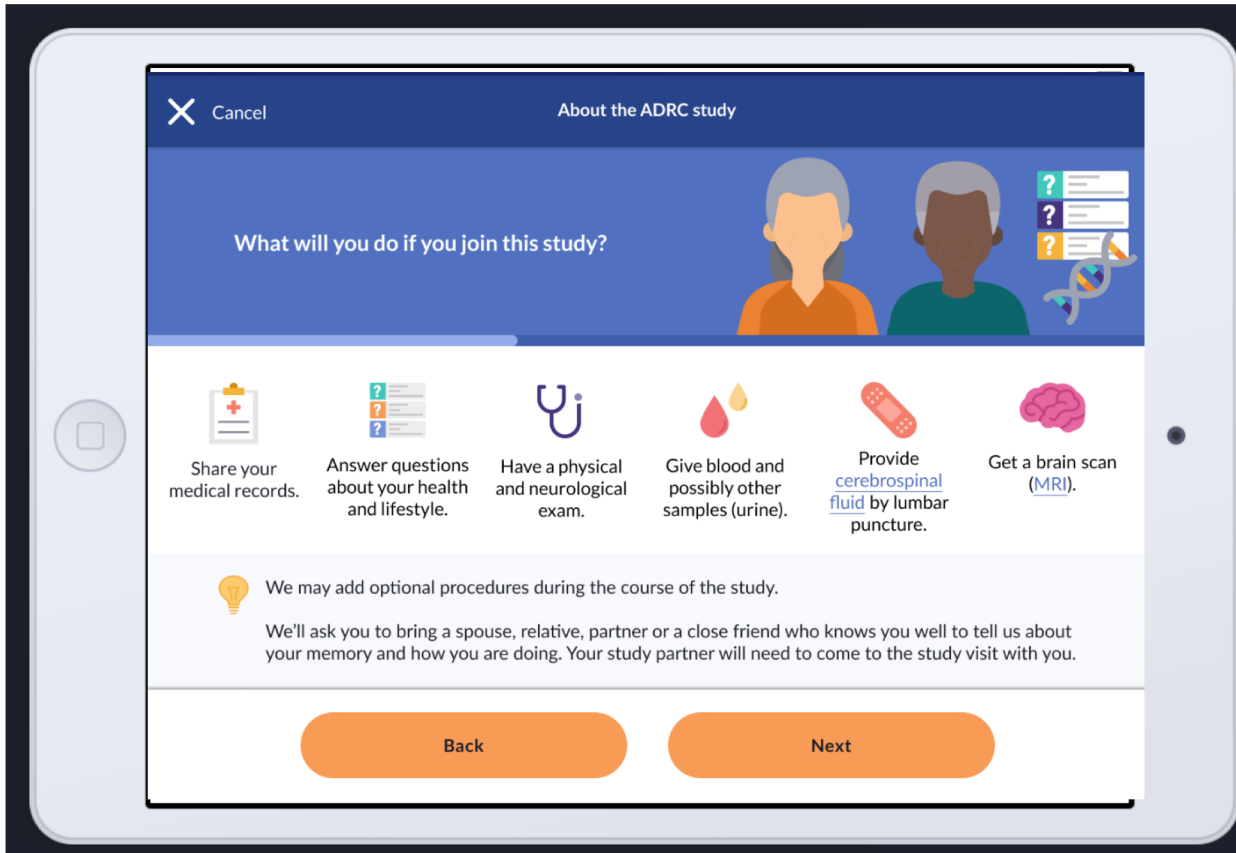
1. Must provide information any “reasonable person” would want to know (§__.116(a)(4));
2. **Must begin with “a concise and focused presentation” of “key information... organized and presented in a way that facilitates comprehension” (§__.116(a)(5)(i)); and**
3. Must present information in “sufficient detail,” but not “merely provide lists of isolated facts” (§__.116(a)(5)(ii)).

eConsent Introduction- About the study

- Why this research?
- What will I do?
- How long?
- Most common risks?
- What's next?



Layered Information



— **Navigation**

— **Main Concept + Visual**

Graphics demonstrate and reinforce the information provided in text.

— **Text Information Area + Icons**

Graphics demonstrate and reinforce the information provided in text.

— **Hyperlinks**

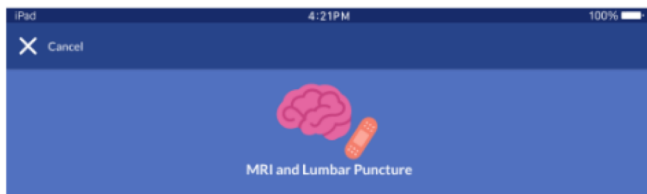
Opens to more information

— **Instruction area**

eConsent Narrative

Self-guided exploration





We will:

- Take images of your brain with a scanner. This is called an MRI.
- Get a sample of your cerebrospinal fluid via a lumbar puncture.

These procedures may help scientists find clues for why some people get Alzheimer's disease and others do not.

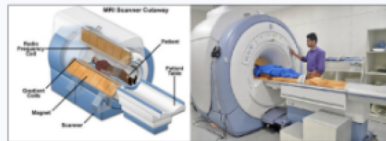
The MRI and lumbar puncture procedures will take about 2 hours each. They can be done on the same day or on different days but within 3 months of your first visit.



What is an MRI scan?

An MRI is a detailed picture of blood flow obtained with a scanner. To take the picture the MRI machine passes a magnetic field through the body. The scanner looks like a large metal doughnut. To get a brain image, your entire upper body (head down to mid-thigh) must be placed inside the "hole" of the machine. You must lay down on the MRI table and stay as still as possible during the scan or else the picture will be blurry. The MRI machine can make loud noise. We will give you disposable earplugs to reduce the noise.

You cannot eat or drink anything other than water for 4 hours before the MRI. You can take your usual medications with water only. If you are a smoker, we will ask you to stop nicotine at least one hour before the MRI, as nicotine may affect blood flow.



[Learn more about MRI scan procedure.](#)



What is a Lumbar Puncture?

A lumbar puncture collects a small amount of **cerebrospinal fluid (CSF)** from your lower back. Scientists will measure changes in the CSF. Some changes may be early signs of memory loss.

The experienced clinician will perform the lumbar puncture. The clinician will do a physical exam to make sure you have no conditions that would make spinal fluid collection unsafe. Then, we will numb your lower back with lidocaine. This is a medication we apply to your skin. The clinician will use a very thin needle to collect about 4.5 teaspoons of fluid. We will analyze about 1 mL of fluid for red and white blood cell count. We will keep the remaining fluid for future research.

You cannot eat or drink anything except water for 4 hours before the lumbar puncture. You can take your usual medications with water only.



[Learn more about the Lumbar Puncture Procedure](#)

Next

Scroll to view more



MRI Scan Procedure



The MRI procedure starts with a questionnaire to make sure it is safe for you to go inside the machine.

To take the picture the MRI machine passes a magnetic field through the body. People with metallic implants (prostheses, shrapnel, or aneurysm clips) or electronic implants (cardiac pacemakers or implanted hearing devices) cannot have an MRI. If you have metal in your body for any reason, we may take an X-Ray as a safety precaution before doing the MRI.

We'll make you as comfortable as possible. You will lay down on the scanner table. Your head will be held in place by foam padding to help you keep still during the scan.

The entire procedure will take about 1 hour to complete. We'll take several images. Each one may take a few seconds to 10 minutes. You will be able to talk to the scan operator through an intercom in between scans.



Cerebrospinal fluid

This is fluid that is in direct contact with the brain and spinal cord. This fluid can help scientists learn about changes in the brain that happen before and after memory loss. A sample of this fluid can be taken via lumbar puncture in the lower back. An experienced clinician uses a very thin needle (about the size of fishing line) to collect this fluid.



Lumbar Puncture Procedure

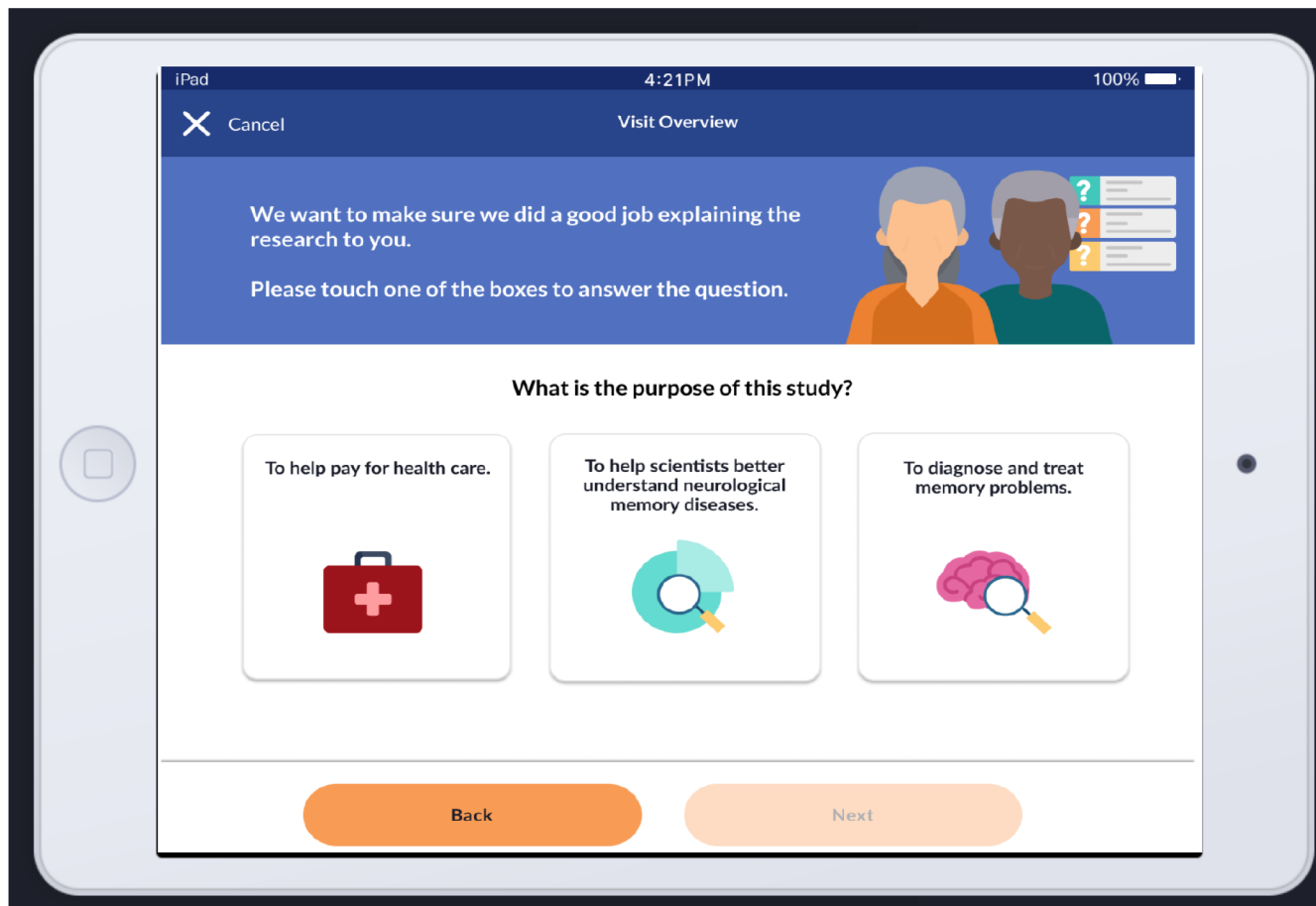
The procedure starts with a questionnaire to make sure it is safe for you to proceed.

Position: You can sit upright with your arms and head resting on a pillow on a table. If you prefer, you may lie on your side with your knees as close to the chest as possible.

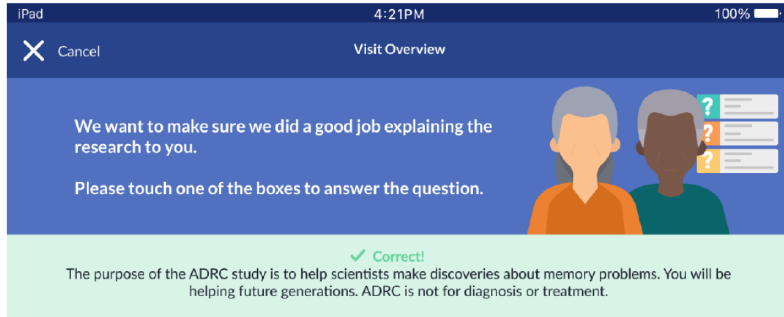
Your lower back will get numb with lidocaine medication. The clinician will use a very thin needle to collect CSF below where the spinal cord ends. The needle is 1/48 of an inch wide [0.5 mm, about the size of fishing line], and 3.5 to 5.9 inches long. The clinician will collect about 4 1/2 teaspoons (22 mL) of fluid. This will take 30-40 minutes. .



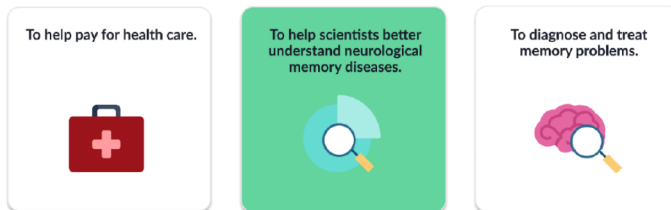
After the fluid is collected, you will lie on your back for 20 minutes.



Formative Evaluation



What is the purpose of this study?

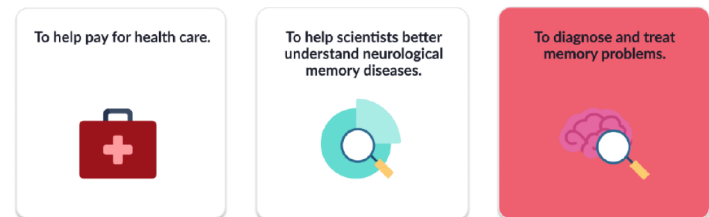


[? Ask a coordinator](#)

Next



What is the purpose of this study?



[? Ask a coordinator](#)

Next

iPad










4:21PM


100%

X

Cancel

What you can expect if you choose to participate in this research study

<div><div>✓</div></div> <div>Visit Overview</div>	<div><div>✓</div></div> <div>General Procedures</div>	<div><div>✓</div></div> <div>MRI and Lumbar Puncture</div>
<div><div>✓</div></div> <div>Risks and Benefits</div>	<div><div>✓</div></div> <div>Your Privacy</div>	<div><div>✓</div></div> <div>issues to Consider</div>
<div><div>✓</div></div> <div>Cost and Compensation</div>	<div><div>✓</div></div> <div>Future Research</div>	<div><div>✓</div></div> <div>Think It Over</div>



Review your Quiz Results & Participation Agreement

View

Quiz Question Review

- ✓ 1. What is the purpose of this study?
The purpose of the ADRC study is to help scientists make discoveries about memory problems. You will be helping future generations. ADRC is not for diagnosis or treatment.
- ✗ 2. What procedure is NOT part of this study?
This research includes blood measurements and a memory and thinking test. It does not include an aerobic endurance test.
- ✓ 3. Which statement is true?
The MRI Machine passes a magnetic field through the body. You must lay down on the MRI table and stay as still as possible during the scan or else the picture will be blurry.
- ✓ 4. Are there risks of participating in ADRC?
There are possible risks, discomforts, and annoyances with any research study. All deserve careful thought. There may also be some risks that we do not know about.
- ✗ 5. Are there risks of having a brain scan (MRI)?
There are possible risks, discomforts, and annoyances with any research study. There are small risks having a brain scan. For example, the MRI machine uses a magnetic field. This can cause malfunction of metallic and electronic implants. Some people may feel claustrophobic and anxious during the procedure.
- ✗ 6. How will my privacy be protected?
Your privacy is very important to us. We will protect your personal information to the best of our ability and the extent permitted by law. We will take many steps to protect your privacy. We also obtained a Certificate of Confidentiality for this study to refuse requests to give out study information that could identify you without your written consent.
- ✓ 7. Do I have to take part in the research study?
Taking part in the study is your choice. You can choose to join or not. No matter what you decide, now or in the future, it will not affect your medical care.


Next


Recap

iPad


4:21PM

100%







Participation Agreement




Scientists can use information gathered during my clinical and research evaluations for research purposes. They may put my information in an electronic database..



I agree to the collection and use of my blood, cerebrospinal fluid, and other samples for research purposes.



I agree to allow my samples to be stored for future testing, including DNA (genetic) tests.



I agree that the scientists may contact me to update my research record or to ask me about participating in new research projects.

Next



Thank you for agreeing to participate in the ADRC research study!

You have successfully gone through the consent process. Please pass the device to your coordinator for next steps.

Thank you

Sage is hiring
Join the team!



<http://sagebionetworks.org/join-the-team/>

Christine Suver
Director Research Governance & Ethics
christine.suver@sagebase.org