

February 10, 2016

FROM : Schulman IRB ("Schulman" or the "Board")
TO: All sites that receive Schulman approval to conduct this protocol
SUBJECT: Recruitment/Study-Related Material
IRB NO.: 201504940;
SPONSOR : American College of Radiology Imaging Network
PROTOCOL NO.: ACRIN 7155 IDEAS
CONTACT :

The following item was reviewed by Expedited Review, as referenced below, and received a decision of

Approved for use ONLY in its entirety

Material Type : Brochure	Material Item# : MA1600813-1
Description : Version Date 05 Feb 2016	
Submitted By : Sponsor	Received Via : Email
Received Date : 02/10/2016	Review Date : 02/10/2016

Translated Recruitment/Study Related Materials will be distributed to you under separate cover.

Approved and/or Acknowledged Recruitment/Study-Related materials should not be used or distributed to study subjects until you have received an approval letter from Schulman to conduct this study.

Acknowledged material includes, but is not limited to, copyrighted documents, some subject instructions, standardized questionnaires, etc.

Any variation of approved or acknowledged materials (other than contact information) must be resubmitted for review.

PLEASE REFERENCE MATERIAL ITEM NUMBER **MA1600813-1** ON ALL CORRESPONDENCE

WebPortal/Paperless

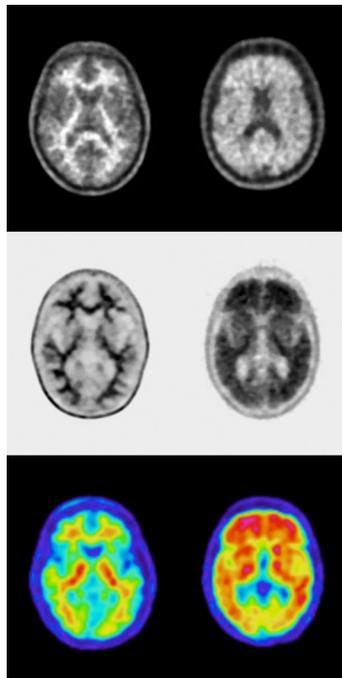


iDEAS

**Imaging Dementia—Evidence
For Amyloid Scanning**

About the IDEAS Study

A physician who specializes in dementia can help decide if the IDEAS Study is right for you. Over 18,000 Medicare patients are expected to be in the study. For the study, you will have an image of your brain taken, called an amyloid PET scan, and you will also have a follow-up visit. The physician who enrolled you in the study will fill out two forms about your diagnosis and treatment plan: one before the scan and another one 90 days after it. Your Medicare claims information will be collected for up to three years.



What are my rights if I take part in this research study?

The decision to be in the study is up to you. You can choose to not take part or you may stop for any reason. If you decide not to be in the study or to stop after you already started, you may do so without penalty or loss of benefits to which you are otherwise entitled and without any effect on your future medical care. If you stop taking part in the study, any data collected will belong to the study and may be used for research.

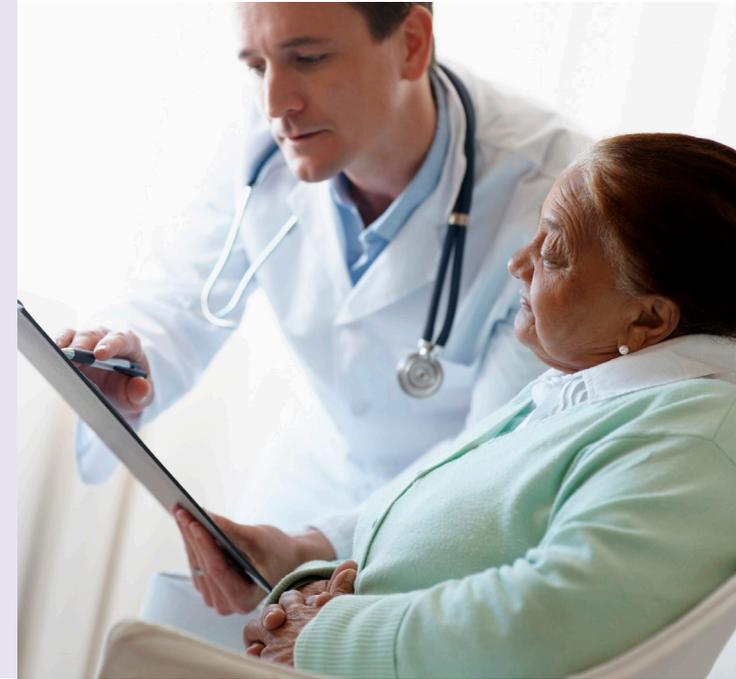
How will my privacy be protected?

All information about you needed for this study will be kept private, confidential, and secure, including any information sent over the Internet. Your personal information will be kept separate from any of the images or information about them and stored at the American College of Radiology Imaging Network (ACRIN) headquarters. Information about you would only ever be given out without your consent if required by law. If any information from the study is published or presented at scientific meetings, your name and other personal information will not be used. The scientists doing the study will do their best to make sure that your information will be kept private, but they cannot guarantee total privacy.

**To learn more, go to:
IDEAS-Study.org/patients**

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alzheimer's  association®

The IDEAS Study is directed by the Alzheimer's Association®; sponsored and managed by the American College of Radiology (ACR) and the ACR Imaging Network (ACRIN); and advised by the Centers for Medicare and Medicaid Services (CMS).

Purpose of this research study

This study is called the IDEAS Study. It stands for Imaging Dementia—Evidence for Amyloid Scanning (IDEAS) Study. In this study, scientists want to learn how images of the brain may be able to help your doctor treat your condition, and if that treatment may lead to better results. Scientists experienced in research are conducting the study, along with the Alzheimer's Association and the American College of Radiology Imaging Network (ACRIN).

Health results for you

The IDEAS Study will focus on brain images called amyloid PET scans. PET stands for Positron Emission Tomography. These scans can show if amyloid plaques are building up in the brain. Amyloid plaques are sticky clumps of protein in the brain. Plaques are associated with Alzheimer's disease, but can also be seen with aging and other brain disorders. The presence or absence of amyloid plaques will help your doctor determine the likelihood that your symptoms are caused by Alzheimer's disease.

If the plaques are present, PET imaging will highlight them. A radiopharmaceutical, which is also called a radioactive tracer, will stick to the plaques for a short time, allowing the plaques to be seen. The tracer has been approved by the U.S. Food and Drug Administration (FDA), and will be injected into your blood through an I.V. for the amyloid PET scan. Medicare has agreed to cover the cost of these scans for this research study.

You may be eligible to participate in the IDEAS Study if you:

- Are a Medicare beneficiary, 65 years of age or older.
- Have ongoing memory problems or confusion and your doctor has not found the cause of your symptoms.
- Have a medical history and cognitive testing that supports the diagnosis of either dementia or mild cognitive impairment, but the cause is not clear.
- Have possible Alzheimer's disease, but your signs and symptoms are unusual.

How do I get involved?

To be part of the study, you will need to:

- 1) Be evaluated by a doctor who is an IDEAS Study dementia specialist who can determine if you can participate in this research study.
- 2) Visit an IDEAS Study PET facility for a brain amyloid PET scan upon physician referral. This could be at a hospital or an outpatient center.
- 3) After the amyloid PET scan, complete a follow-up visit with the dementia specialist to discuss the results.



How will I benefit from the study and will it cost me anything?

- Your referring dementia specialist will receive the results of your amyloid PET scan, discuss the scan results with you, and may use that information in planning your future care.
- Your amyloid PET scan will be covered by your Medicare plan. As with any medical service covered by Medicare, you will still be responsible for any deductible or co-payment required for the service. The amount you would have to pay will depend on whether or not you have supplemental insurance or other coverage for your deductible and co-payments.

Are there risks involved in the IDEAS Study?

All research studies, including the IDEAS Study, may involve some risks associated with participation.

The brain imaging (amyloid PET scan) is FDA-approved and is not considered experimental. However, there are risks associated with this imaging test including:

- Exposure to low doses of radiation.
- Possible pain at the injection site.
- Possible discomfort from enclosure in a small space during the scan.

And even though every effort will be made to protect your privacy, there is a risk of disclosure of personal health information.

To learn more, go to:
[IDEAS-Study.org/patients](https://www.idealstudy.org/patients)