

Informed Consent - Radiologist/Nuclear Medicine Physician

Imaging Dementia—Evidence for Amyloid Scanning (IDEAS) Study:
A Coverage with Evidence Development Longitudinal Cohort Study

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Schulman Institutional Review Board (Schulman) has approved the information in this consent document and has given approval for the study doctor to do the study. An institutional review board (IRB) is an independent committee established to help protect the rights of research subjects. This does not mean the IRB has approved your participation in the study. You must think about the information in this consent document for yourself. You must then decide if you want to be in the study.

This study is being conducted by the American College of Radiology Imaging Network. The national study Principal Investigator is being paid by the American College of Radiology Imaging Network to conduct the study. You may ask any questions to assure yourself that these benefits to your study doctor have not overly influenced their conduct of this research study.

The purpose of the Imaging Dementia—Evidence for Amyloid Scanning (IDEAS) Study is to prospectively examine how the use of amyloid PET scans impacts the management and outcomes of patients with mild cognitive impairment (MCI) or dementia of unknown etiology.

The Centers for Medicare & Medicaid Services (CMS) is providing coverage for the amyloid PET performed for this project under a program known as “coverage with evidence development” (CED). As a condition of payment for amyloid PET, CMS requires that the imaging be completed within 30 days after submission of the Pre-PET Form by the referring dementia specialist, that your PET report and a completed electronic case report form related to your findings be submitted within 7 days after amyloid PET, and that the referring dementia specialist submit case report forms before and approximately 90 days after the amyloid PET. The information is entered into a secure database maintained by the IDEAS Study. The IDEAS Study will notify you and the PET facility that performed the amyloid PET when all required data are received, indicating that it is appropriate to submit a claim for payment to CMS.

Participating in the IDEAS Study is your choice. Your participation in the research component is voluntary. You may choose not to participate. If you agree to participate, you may discontinue participation at any time. If you withdraw from the study, no new data will be collected from you for research purposes. Your decision not to participate or to withdraw from the study will not involve any penalty or loss of benefits to which you are otherwise entitled, except for inability to perform professional interpretations of amyloid PET scans performed on patients enrolled in the IDEAS Study. If you agree to participate, the IDEAS Study investigators will use the information you provide for research purposes. The patient and the referring dementia specialist also will be asked to allow their information to be used for the same research purposes.

You are being asked to sign this document to show you agree to the following: a) completing the amyloid PET interpretation and completing the Amyloid PET Assessment Form within the defined timeline; and b) following the procedures for submitting results information to the IDEAS Study database. If after choosing to sign this consent you no longer wish to participate in the IDEAS Study, you will need to provide written notification to the research team documenting removal of your consent.

What are the purposes of the study?

There are two main purposes of this study:

1. To assess how amyloid PET results impact the management of patients who qualify for amyloid PET based on standardized Appropriate Use Criteria. This will be assessed largely on the basis of data you will supply before and after amyloid PET.
2. To assess the rates of hospital admissions and emergency room visits over 12 months in subjects enrolled in the main IDEAS Study cohort (who have had amyloid PET) compared with a matched control group (who have not had amyloid PET). This will be assessed by use of CMS claims, both for patients enrolled in the study who undergo amyloid PET and matched controls who do not.

Additional data collected during the IDEAS Study will allow for multiple secondary and exploratory aims related to diagnosis, costs, and overall patient management.

What am I being asked to do for the project?

You are being asked to participate in this project because you have experience and training in amyloid PET of the brain.

If you choose to participate, you will need to complete an Amyloid PET Assessment Form and submit your PET report, which are necessary for the IDEAS Study and for Medicare payment of the PET scan. If you choose to participate in the research study, the information you provide will become part of the research data. The Amyloid PET Assessment Form, which must be completed within 7 days after the PET scan, will ask you questions about the imaging study that will be entered into the database for study analysis. By signing this consent, you are agreeing to complete and submit the required form within the timelines prescribed in the study protocol.

How long will I be in the study? What will happen during the study?

The IDEAS Study is expected to enroll 18,488 patients with MCI or dementia over a period of 24 months. You will be a participating radiologist/nuclear medicine physician for as long as you choose to remain in the study or until patient accrual is finished.

What are the risks?

There are no known risks of participating in this type of study other than the potential for loss of confidentiality. You may find participating in this study, viewing web-based educational content, attending meetings associated with the study conduct, and completing the electronic case report forms for the study to be additional work added to your routine clinical responsibilities. The information collected for the study will be de-identified at time of collection.

How will I benefit from the study?

There may be no direct benefit to you. However, you may benefit from increased knowledge about amyloid PET's influence on clinical decision making when the results are available. In the future, the knowledge learned during this study could help guide the appropriate use of amyloid PET in patients whose conditions are difficult to diagnose.

What happens if I do not choose to join the study?

The decision to participate or not is your own. No matter what decision you make, and even if your decision changes, there will be no penalty to you. You can choose to stop at any time by informing the study team in writing. If you choose not to participate you will be unable to interpret amyloid PET scans for Medicare patients enrolled in the IDEAS Study.

How will my privacy be protected?

We will do our best to make sure that the patient and management information obtained during the course of this research study is kept private. However, we cannot guarantee total privacy. Study information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

How will confidentiality be maintained?

The IDEAS Study database will contain only unique identifiers for you and your patients to protect your identities. The study investigators will need to know your patients' identities in order to coordinate collection of Medicare claims data for the study. Your patients will consent to the release of this information, and the personal health information (PHI) required for this part of the study will be kept in a database dedicated to PHI, which will be separately housed from the primary database used for analysis purposes.

Who will be allowed to see identified data?

The radiologist/nuclear medicine physician and authorized members of his/her staff, the ACRIN data management center, the statistical team coordinating collection of claims data from CMS, and members of the IRB will have access to the records. De-identified information may be provided as required by law.

Whom can I call with questions, complaints, or if I'm concerned about my rights as a research subject?

If you have questions, concerns, or complaints regarding your participation in this study, or if you have any questions about your rights as a participating radiologist/nuclear medicine physician, you should speak with the study Principal Investigator or contact the IDEAS Study project management office at www.IDEAS-Study.org.

If you have any questions about your rights as a research subject, and/or concerns or complaints regarding this research study, you should write to Schulman Institutional Review Board, 4445 Lake Forest Drive - Suite 300, Cincinnati, Ohio 45242, or call toll-free 1-888-557-2472 during business hours Monday - Friday 8:00 a.m. to 6:00 p.m. EST.

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This website will not include information that can identify you. At most, the website site will include a summary of the results. You can search this website at any time

My signature for participating in the study

I have read this consent form or had it read to me. I have had the opportunity to discuss this consent with the study team, as necessary, and my questions have been answered. I will be given a signed copy of this form. I agree to take part in the study.

Participant's name (printed): _____

Participant's signature: _____

Date of signature: _____