

Jan 26, 2022



"New IDEAS is on track to be among the most racially and ethnically diverse Alzheimer's disease clinical studies ever conducted. With the launch of the New IDEAS PET Coinsurance Reimbursement Program, we are removing a potential financial barrier to participation in the study, which may facilitate an even greater increase in enrollment of traditionally underrepresented participants," said Maria C. Carrillo, PhD, Alzheimer's Association Chief Science Officer and Co-Investigator of the New IDEAS Study.

New IDEAS Surpasses Milestone of 2,000 Patient Registrations

Thanks to the activated dementia practices and PET imaging facilities, over 2,000 patients are now registered into New IDEAS, and 1,537 patients have received an amyloid PET scan.

Coinsurance Reimbursement Program is officially active as of Jan. 1, 2022!

What Is the New IDEAS Coinsurance Reimbursement Program?

New IDEAS will now pay the coinsurance amounts that study participants would otherwise owe for the Medicare-reimbursable amyloid PET scans provided during the study. Study

participants who have not received their amyloid PET scan as of Jan. 1, 2022, are eligible to have their amyloid PET scan coinsurance obligations submitted to the study sponsor for reimbursement. Payment will be made directly to the PET facility. Full program details can be found in the [New IDEAS Coinsurance Reimbursement Policy](#) and the [Coinsurance Reimbursement Training Module](#). All participating dementia practices and imaging facilities must review and comply with this policy. Find answers to commonly asked questions in the [Coinsurance Reimbursement Program FAQ](#).

How Are Participating Dementia Practices Impacted?

1) Updated Informed Consent Document — All Institutional Review Board (IRB)-approved dementia practices will receive a separate notification from Advarra IRB for approval of an updated informed consent document. Activated dementia practices must consent patients on the new Informed Consent Form (ICF) document. Per the IRB of record's determination, currently enrolled study participants do not need to be re-consented with the updated and IRB-approved ICF.

2) Updated recruitment materials for use — The New IDEAS Study team received IRB approval for updated patient recruitment materials for use in clinics and communities. Prior to utilizing the recruitment and informational materials provided below, please review the [Instructions for Patient-Facing Recruitment and Informational Materials](#). This document provides a brief description of each material, its purpose and suggestions for use. Available resources can be found on the [study website](#) and currently include:

- [New IDEAS Participant Brochure Packet](#)
- [New IDEAS Participant Flyer Packet](#)
- [New IDEAS Participant Poster Packet](#)
- [New IDEAS Study Info Sheets](#)
- [New IDEAS Amyloid PET Scan Info Sheets](#)
- [Patient-Facing Website](#)

3) Updated case report form (CRF) packet and study portal — The study team recently released an update to the study's electronic data capture portal, effective Dec. 15, 2021. PDF versions of the updated case report forms can be found on the [study website](#). Notable updates for dementia practices include:

- Supplemental insurance data collection on the Case Registration Form.

How Are PET Imaging Facilities Impacted?

1) Study participants who have not received their amyloid PET scan as of Jan. 1, 2022, are eligible to have their amyloid PET scan coinsurance obligations submitted to the study sponsor for reimbursement.

2) Patients scanned on or after Jan. 1, 2022, must not receive a bill for coinsurance or copayment associated with their amyloid PET Scan. The PET facility is responsible for implementing facility-level operational changes to ensure patients eligible for coinsurance reimbursement do not receive a bill from the PET facility. Additionally, facilities must not collect amyloid PET scan copayments from the patient at time of service.

3) Imaging facilities already under agreement with the ACR must fully execute Amendment #1 before payment for reimbursable patient coinsurance obligations are remitted. The study operations team emailed the amendment document to your facility on Dec. 15, 2021.

4) Updated CRF packet and study portal — The study team recently released an update to the study electronic data capture portal, effective Dec. 15, 2021. PDF versions of the updated case report forms can be found on the [study website](#). Notable updates for

imaging facilities include:

- A mandatory new user role on the Facility Registration Form — Facility Finance User.
- The Coinsurance Reimbursement Form — Available for all participants once the PET scan completion form is submitted on or after Jan. 1, 2022.
- The Facility Finance tab — Allows submission of necessary bank and tax information. Reimbursement will only be remitted via electronic funds transfer.

Community Engagement and Recruitment Support

The New IDEAS Study hosted a Recruitment and Engagement Webinar on Oct. 28, 2021, titled: "Informed Consent Best Practices: Essential Elements and Cultural Considerations."

All physicians and staff engaged in recruitment and consenting processes are encouraged to review [the webinar recording](#) and additional resources found in the study's [Recruitment Toolkit](#).

The New IDEAS Recruitment Support Team is pleased to offer one-on-one consultations to support participant recruitment. Emails to sites will begin the week of Jan. 24. In addition to consultations, the New IDEAS team is requesting feedback from Site Investigators about challenges and successes with recruitment, especially regarding minority recruitment. For information and resources on minority recruitment training and strategies, please visit the [New Ideas Study website](#). If you have any questions, would like a consultation or want to share information, please contact our team at newideas_recruitment@vumc.org.

The New IDEAS Recruitment and Engagement Team is seeking additional volunteers to serve as Study Champions to promote the New IDEAS Study.

Champion duties include:

1. Deliver study materials about the New IDEAS Study.
2. Outreach to the community about the importance of minority participation in research.
3. Partner with local organizations to provide education and host events to support study awareness and New IDEAS Study enrollment.

Champions must:

1. Live in one of the following nine metro areas — Chicago, Dallas, Houston, Kansas City, Los Angeles, Miami, Philadelphia/New Jersey, San Diego, Washington DC/DMV.
2. Serve a one-year commitment.
3. NOT be directly working on the New IDEAS study as an employee of a participating site or facility.

If you or someone you know may be interested in learning more information about ways to get involved, contact the community engagement specialists, Andrea Mendoza at andrea_mendoza@med.unc.edu or Tammy Jacobs at tammyjac@ad.unc.edu.

Medicare Billing Tips:

1) Detailed instructions on proper Medicare billing processes can be found on the [study website](#).

2) Participating imaging facilities must accept referrals of Medicare Advantage (MA) participants, if the facility is contracted with that patient's plan. In general, providers that accept Medicare cannot add restrictions that would discriminate against Medicare

beneficiaries ([42 CFR § 489.53](#)). If a provider accepts a MA plan, it cannot discriminate by selectively accepting referrals for Medicare patients. However, providers do not have to accept all Medicare Advantage plans. Any provider who violates this condition of participation can be reported to the CMS and their respective MA plan.

3) All participating referring dementia providers and radiologists/nuclear medicine physicians must be enrolled in the Medicare Patient Enrollment Chain and Ownership System (PECOS). This is a requirement set forth by the study protocol and CMS to bill for services provided to Medicare beneficiaries.

Additional Study Reminders

Biorepository and Sample Collection — Active study participants will receive saliva collection kits in the mail after completing the amyloid PET scan. Please remind patients that collection and return of saliva samples is a required task of study participation. Participants who consented into optional blood collection will receive a combined collection kit in the mail. The kits contain detailed instructions, in both English and Spanish, on how to complete the collection process for both [saliva collection](#) and [blood collection](#). Dementia practices are encouraged to utilize these documents during the informed consent process to ensure understanding by the study participant. **Note:** The biorepository lab staff are currently working through a backlog of shipments due to increased accrual volume. Participants should be instructed to remain patient while waiting for their kits.

Participant Eligibility — Per protocol, all inclusion and exclusion criteria must be confirmed by the referring dementia specialist and/or the participant's medical records, prior to registration. Study participants must not have previously received an amyloid PET scan prior to participation in New IDEAS.

Participation in the original IDEAS Study automatically excludes a patient from also participating in New IDEAS.

Contacts for Your Questions

A large multicenter national study such as New IDEAS requires compartmentalized communication streams to respond in a timely, accurate manner. Below is a summary of study email addresses, accompanied with a description of support services.

- newideas@acr.org — Primary study email directly to the ACR operations team. Topics and questions related to protocol specifics, trainings and IT operations should be directed here.
- newideas-data@acr.org — Data management-related topics and questions such as data change requests and navigating the case report forms within the study portal.
- newideas-contracts@acr.org — Contracting topics and questions specifically related to study legal agreements for participation.
- newideas-regulatory@acr.org — Regulatory topics and questions such as ICF review, assistance with Advarra IRB submissions, protocol deviations, etc.
- newideas_recruitment@vumc.org — Direct email to the recruitment and community engagement team. Topics such as best practices and additional support in recruitment efforts should be directed here.
- triad-support@acr.org — TRIAD image upload questions and/or requests for assistance should be directed here.

Top Accruing Sites

Total Registrations To Date	Underrepresented Minority Participant (URMP) Registrations to Date
1) Baylor AT&T Memory Center (Claudia Padilla, PI; Dallas, TX)	1) Alok Bhattacharyya, MD — Fremont, CA
2) Neuro-Pain Medical Center (Perminder Bhatia, PI; Fresno, CA)	2) Neuro-Pain Medical Center (Perminder Bhatia, PI; Fresno, CA)
3) Alok Bhattacharyya, MD — Fremont, CA	3) Neurological Medicine, PA (Nabeen Hussain — Greenbelt, MD)

IDEAS - Imaging Dementia - Evidence for Amyloid Scanning

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