

Jun 01, 2022



The New IDEAS Study is rooted in a core purpose of studying the association between amyloid PET imaging and patient-centered outcomes in disproportionately affected patient populations who bear the greatest burden of dementia. Inclusion of traditionally underrepresented populations in clinical research is imperative to ensure that study findings are generalizable to all people in the United States. Study leadership commends the active dementia practices for their enrollment success and for their continued enthusiasm and commitment to the New IDEAS Study.



[View enlarged image](#) **New IDEAS Surpasses 3,000 Patient Registration Milestone**

Thanks to the activated dementia practices and PET imaging facilities, over 2,600 registered participants have now received an amyloid PET scan.

New IDEAS Implements Temporary Enrollment Pause on the “All Other Races/Ethnicities” Cohort

On March 1, 2022, the New IDEAS Study implemented a temporary enrollment pause for

the participant cohort representing the 3,000 patients from other racial and ethnic categories. Pending periodic review of the study's enrollment, accrual into all study cohorts is expected to resume on or around Sept. 1, 2022. The enrollment pause applies to all participating New IDEAS sites across the country, including newly activated dementia expert sites. Review the [Temporary Enrollment Pause Memorandum](#) and [FAQs](#) to learn more.

How Are Participating Dementia Practices Impacted?

1. New IDEAS Portal Updates — Starting March 1, 2022, the New IDEAS Portal application automatically blocks registration of individuals who self-identify into the "all other race and ethnicity" cohort. A red error message will appear, and submission functionality on the Case Registration eCRF will not be available. The study encourages practices to keep screening logs of potentially eligible patients who could be enrolled once accrual to all cohorts is available again.
2. Re-registration Process — Re-registration of patients is allowed when the original registration date occurred prior to March 1, 2022. If a patient needs to be re-registered, the dementia practice should contact the New IDEAS Operations Team at newideas@acr.org to request a re-registration waiver.

How Are Participating PET Imaging Facilities Impacted?

The temporary enrollment pause has no impact on PET facility operations. PET facilities should schedule and scan a New IDEAS participant within 60 days of the Pre-PET form submission date regardless of the participant's race/ethnicity.

New IDEAS Aims to Improve Biorepository Sample Collection Process

The New IDEAS Biorepository for saliva and blood remains a priority of the study to aid future research of Alzheimer's disease biomarkers. The dementia practices in New IDEAS play a crucial role in educating participants about biosample collection. Together, through patient education and operational changes, we can reach our biosample collection goals to help answer important scientific questions in Alzheimer's disease research.

What Is the New IDEAS Study Doing to Improve the Current Sample Collection Process?

1. New Portal Functionality for Tracking Sample Shipments and Email Reminders — Practice staff can now view tracking information for patient saliva and blood shipments in the New IDEAS Portal. Reminder notifications will be sent to practice staff when kits are shipped to patients
2. Patient-facing Biosample Email Template for Increased Patient Awareness — The New IDEAS Study developed an [email template](#) for practices to share with patients when kits are mailed. Practice staff members are encouraged to reach out to patients when kits are shipped.
3. Example Saliva and Blood Kit to be Mailed to Practices for Consent Discussion — In the coming weeks, a biosample collection example kit will be shipped to each active dementia practice to serve as a visual example or demonstration model for patients during the informed consent process
4. Newly Hired Biorepository Staff to Help Decrease Shipment Delivery Timeline — With help from new biorepository staff members, the timeline for biosample collection kits is expected to decrease in the coming months to ensure participants receive their biosample kit as close to their PET scan date as possible.

Important Biorepository Reminders:

1. Saliva Collection to be Completed by all Study Participants — Saliva collection is a part of the main study protocol for New IDEAS. Therefore, all 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.
2. Share Study Helpline with Patients — Patients, family and caregivers should contact the New IDEAS Study Patient Helpline at 1-866-507-7254 or email newideas-participant@alz.org if they need assistance with the saliva collection process or help scheduling a blood draw appointment.
3. Track Biosample Completion by Case ID — Practice staff should identify and notify patients who have not yet completed the biosample collection process. To view patient status, click on the Biosample Tab by Case ID in the New IDEAS Portal.

Printed Study Recruitment Materials Available for Participating Dementia Practices

The New IDEAS Study Team is excited to announce the availability of printed recruitment materials to increase recruitment efforts across the country. The New IDEAS Recruitment and Community Engagement Team developed a comprehensive suite of recruitment and informational materials to help promote diversity and inclusion and to authentically reach the study's underrepresented patient populations. Multiple versions of the materials ensure that the study materials are both culturally sensitive and easily understood by all patients.

How Do I Obtain Recruitment Materials for My Practice or Community Event?

1. New IDEAS Study Recruitment Toolkit Shipped to Active Practices — Practices activated prior to April 1, 2022, received a New IDEAS Study Recruitment Materials Kit containing a comprehensive suite of recruitment and informational materials. Review the [Site Instructions for Patient Facing Recruitment and Informational Materials](#) to learn how to use these materials to recruit patients in your practice. If your site did not receive a welcome packet, or was activated after April 1, 2022, email newideas@acr.org.
2. Newly activated practices will receive their recruitment materials kit in the coming weeks.
3. Activated practices may request additional hard copies of the Institutional Review Board (IRB)-approved recruitment materials by completing the [Recruitment Material Request Form](#).
4. Electronic versions of recruitment materials are available online on the [study website](#).

Spanish Language Informed Consent Forms Now Available to All Practices

All participating dementia practices have now received a translated version of their IRB-approved informed consent form. This translation was paid for by the study, free of charge to the dementia practices. Please log into your site's [Advara IRB CIRBI portal](#) to access and download the translated, approved document.

Transportation Assistance to the Amyloid PET Scan Appointment

The study team received community feedback that a common barrier to participation in New IDEAS is transportation to participating PET facilities. Transportation services are not required for facilities to participate in New IDEAS, but rather a proven intervention to eliminating a common healthcare access barrier.

What Is the New IDEAS Study Doing to Help Identify Transportation Assistance for Patients?

1. Facility Finder Updates — Facilities that provide transportation assistance are marked with the statement "(Note: Transportation Assistance Provided)" on the [Facility Finder](#).
2. Transportation Assistance Survey — PET Facilities are encouraged to complete this quick, four-question survey to document patient transportation assistance: <https://www.surveymonkey.com/r/patienttransportationsurvey>.
3. Transportation Assistance Options Provided via Patient Helpline — Practice staff should encourage patients to call 1-866-507-7254 or email newideas-participant@alz.org to learn about transportation options in their community.

PET Imaging Facilities Must Adhere to Coinsurance Reimbursement Program Policy

The New IDEAS Coinsurance Reimbursement Program went live Jan. 1, 2022. All active imaging facilities must review and comply with [New IDEAS Coinsurance Reimbursement Policy](#) to participate in New IDEAS. Full program details can be found in the [Coinsurance Reimbursement Training Module](#). Find answers to frequently asked questions in the [Coinsurance Reimbursement Program FAQ](#). To remain active in New IDEAS, PET facilities must complete all items on the PET Facility Checklist (Slide 15) from the [Program Operational Training Module](#).

Medicare Reimbursement and Billing Guidance

- Important Amyloid PET Scan Exclusion Criteria Clarification — Patients who have a history of amyloid PET scan or who received a scan in the original IDEAS study are not eligible to participate in New IDEAS. The limit for amyloid PET is one scan per patient's lifetime.
- Prior Authorization and/or Medicare Reimbursement Issues — If your facility is currently experiencing issues with prior authorization requests or Medicare reimbursement for amyloid PET scans conducted through New IDEAS, please contact the New IDEAS Operations Team at newideas@acr.org. Detailed instructions on proper Medicare billing processes can be found on the [study website](#). Reminder, the study has [a template letter](#) available for use when communicating with Medicare Advantage Plans. This resource has been proven successful in obtaining prior authorization for coverage.
- PECOS Requirement — 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.
- Facilities Denying Medicare Advantage Plans — 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 an 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.

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 American College of Radiology® 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 informed consent 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) Alok Bhattacharyya, MD (Fremont, CA)	1) Alok Bhattacharyya, MD (Fremont, CA)
2) Baylor AT&T Memory Center (Claudia Padilla, PI; Dallas, TX)	2) Andrew Lerman, MD (Miami, FL)
3) Neuro-Pain Medical Center (Perminder Bhatia, PI; Fresno, CA)	3) Center for Comprehensive Care and Research on Memory Disorders (Chicago, IL)

IDEAS - Imaging Dementia - Evidence for Amyloid Scanning

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