



Alzheimer's Association
and the American College
of Radiology® (ACR®)

New IDEAS Study Update

Oct 04, 2022



139

Activated Dementia Expert Sites

[Find a Dementia Site](#)



126

Activated PET Imaging Facilities

[Find an Imaging Facility](#)



3,724

Total Patient Registrations:

33% of total Black/African American cohort

31% of total Hispanic/Latinx cohort

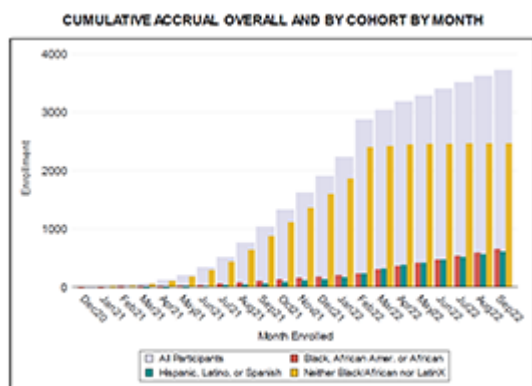
82% of all other race/ethnicities cohort

Study leadership commends the active dementia practices for their continued enthusiasm and commitment to the New IDEAS Study. To complement practice recruitment and engagement activities, the New IDEAS Study Team is leveraging the robust national network of the Alzheimer's Association and partnering with chapters across the country who are involved in minority communities to form local community-based recruitment teams. Local community-based recruitment teams will disseminate recruitment materials to trusted churches, social, civic and cultural groups in Black/African American and Hispanic/Latinx communities. Practices are encouraged to contact the New IDEAS Community Engagement Specialists (newideasstudy.ces@med.unc.edu) and share local events in their area that Study Champions may be interested in attending, to increase

patient referrals to the participating New IDEAS site.



New IDEAS Study Champion hosting a New IDEAS community engagement event at Texas Southern University's Annual Health and Wellness Fair in Houston, Texas.



[View enlarged image](#)

New IDEAS Surpasses 50% Patient Registration Milestone

Thanks to the activated dementia practices and PET imaging facilities, over 2,955 of the registered participants have now received an amyloid PET scan.

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

To achieve the study's prespecified recruitment goals, the New IDEAS Study will extend the enrollment pause on the “all other races and ethnicities” cohort until the study reaches 75% minimum accrual into each of the Black/African American and Hispanic/Latinx cohorts.

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 [FAQ](#) to learn more. Until the study reaches the enrollment goals set forth above, the New IDEAS Study Portal will only allow registration of study participants who self-identify into either the Black/African American or Hispanic/Latinx cohorts to comply with the protocol-defined cohort goals. As a reminder, the temporary enrollment pause has no impact on PET imaging facility operations.

What Resources Are Available to Help With Minority Recruitment and Engagement?

Study leadership expects that all participating sites are actively demonstrating their commitment to the study by engaging in specific efforts to recruit and enroll patients throughout the enrollment pause. You can help the study meet its accrual goals by:

1. Collaborating with the New IDEAS Recruitment Support Team (newideas_recruitment@vumc.org) to evaluate how they can enhance minority recruitment efforts.
2. Utilizing the study website's **Recruitment Toolkit** to learn best practices for minority recruitment and engagement.
3. Requesting additional printed recruitment materials using the **New IDEAS Printed Recruitment Materials Request Form**.
4. Helping increase awareness among primary care providers (PCPs) of the dementia disparities among Black/African American and Hispanic/Latinx patients and potential value of amyloid PET imaging.
 - a. Share PCP contacts with the Study Team to let us do the outreach for you. Complete a brief **PCP Engagement Survey** to share information with our team about PCPs who may be interested in learning more about New IDEAS.
 - b. Contact PCPs directly. Use the following email templates to engage with PCPs in your area (**Template 1** | **Template 2**).
5. Referring volunteers to the New IDEAS Study Community Engagement Specialists (newideasstudy.ces@med.unc.edu) to serve as Study Champions in our community-engaged metropolitan areas defined in the **Study Protocol** and **Study Champion FAQ sheet**.
6. Sharing local community organizations or businesses with the Study Team to help us identify potential partnerships or locations for increasing study awareness. Have an organization in mind? **Complete this short form**.

Ongoing Initiatives by the Study Team to Increase Enrollment and Retention of Black/African American and Hispanic/Latinx Participants

The extension of the enrollment pause will allow for the Study Team to collaborate more closely with practices committed to maximizing efforts of priority populations — Black/African American and Hispanic/Latinx patients. The Study Team will continue to:

1. Engage in site interviews. The study's Recruitment and Support Team will engage in site-specific interviews to identify strategies and resources to improve recruitment efforts.
2. Monitor and report site-level enrollment progress. The Study Team will provide site-level monitoring and evaluation of recruitment progress into each of the study's open cohorts and regular reporting of accrual progress into study cohorts.
3. Develop additional recruitment resources. The study will continue to create and update resources to support minority recruitment such as those linked on the **Recruitment Toolkit**. Activated practices may request additional hard copies of the Institutional Review Board (IRB)-approved recruitment materials by completing the **Recruitment Material Request Form**. Electronic versions of recruitment materials available online on the **study website**. The availability of printed recruitment materials is intended 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.
4. Provide Informed Consent Forms (ICFs) translated into Spanish to all sites. All participating dementia practices have 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. If you have not received a translated version or need a copy of the ICF that is in a language other than English or Spanish, please contact New IDEAS Regulatory Specialist at newideas-regulatory@acr.org.

Coming Soon — New Study Initiatives Expected to Launch in Fall 2022

The Study Team is excited to announce new patient-centered initiatives that are expected to roll out fall 2022. Feedback from our sites, facilities and community stakeholders is

important to the development of New IDEAS initiatives like these. We invite you to connect with the New IDEAS Operations Team (newideas@acr.org) to discuss new, innovate ways to meet our study goals and increase access to care.

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. Practices should expect updates from the Study Team on a new transportation assistance program to help patients get to their amyloid PET scan visit. In the interim, facilities who documented that they provide transportation assistance are marked with the statement "(Note: Transportation Assistance Provided)" on the **Facility Finder**. 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.

Optional In-Home Blood Collection Services

The New IDEAS Biorepository for saliva and blood remains a priority of the study to aid future research of Alzheimer's disease biomarkers. Practices should expect protocol and ICF changes to include an optional in-home blood draw that patients may use instead of going into a local Quest Lab. Additionally, the ACR will contract with Sonora Quest Laboratories to expand in-lab blood draw access to certain regions (e.g., the greater Phoenix, Arizona region).

Protocol Amendment for Removal of Inclusion Criterion "English or Spanish Speaking"

Per the feedback of New IDEAS sites, the inclusion criterion "English or Spanish speaking" for the purposes of informed consent will be removed as a requirement for participation in New IDEAS, effective at the date of IRB approval for the associated protocol amendment. All questions or concerns should be directed to New IDEAS Regulatory Specialist at newideas-regulatory@acr.org.

Important Biorepository Reminders:

1. 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. 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.
4. 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.
5. 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.

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 the **New IDEAS Coinsurance Reimbursement Policy** to participate in New IDEAS. Full program details can be found in the **Coinurance Reimbursement Training Module**. Find answers to frequently asked questions in the **Coinurance 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

- **New** — Facilities will be expected to complete the New IDEAS Claim Check List prior to submitting a request for assistance from the New IDEAS Study's billing specialist. Download the **Claim Check List**.
- **Important Amyloid PET Scan Exclusion Criteria Clarification** — Patients who have a history of amyloid PET scans 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 for 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 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.
- **newideasstudy.ces@med.unc.edu** — Study Champion inquiries, New IDEAS events and community engagement support.
- **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) Center for Comprehensive Care and Research on Memory Disorders (Chicago, IL)
3) Center for Comprehensive Care and Research on Memory Disorders (Perminder Bhatia, PI; Chicago, IL)	3) Andrew Lerman, MD (Miami, FL)

IDEAS - Imaging Dementia - Evidence for Amyloid Scanning

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