

Temporary Enrollment Pause to Support Recruitment, Enrollment and Retention of Underrepresented Populations in New IDEAS

Frequently Asked Questions

How many patients may enroll in the New IDEAS study?

The New IDEAS Study protocol pre-specified that of the 7,000 patients enrolled across the country, 2,000 patients will self-identify as Black/African American and 2,000 as Hispanic/Latinx. The remaining 3,000 patients will self-identify as all other race/ethnicity.

What is the temporary New IDEAS enrollment pause of the “all other race and ethnicity” cohort?

It is a temporary pause to enrollment of patients into the New IDEAS study who self-identify as races other than Black/African American and Hispanic/Latinx. During the time period of the enrollment pause, only individuals who self-identify as Black/African American and/or Hispanic/Latinx will be able to register into the study. The aim is to ensure balance and appropriate representation in the study cohort, and to foster compliance with the study protocol.

To which sites does the enrollment pause apply?

The enrollment pause applies to all participating New IDEAS sites across the country, including newly activated dementia expert sites. Pursuant to the [New IDEAS Enrollment Cap Policy](#) and the clinical study agreement entered between the dementia practices and the American College of Radiology (ACR), “The study reserves the right to cap enrollment for a physician, a dementia practice, or an entire study cohort (i.e. racial and ethnic sub-groups) with immediate effect.”

What is the purpose of temporarily pausing enrollment into the “all other race and ethnicity cohort”?

The overall purpose of the New IDEAS Study is to understand the association between amyloid PET imaging and patient-centered outcomes in a diverse population, specifically Black/African American and Hispanic/Latinx populations who were underrepresented in the original IDEAS Study and bear the greatest burden of dementia. Currently, accrual into the protocol’s pre-specified “all other race and ethnicity” cohort is occurring significantly faster than the Study Team expected and is approaching the maximum enrollment capacity of 3,000 patients. To ensure that the study reaches its enrollment goals for underrepresented populations, this temporary freeze on enrollment of the “all other race/ethnicity cohort” will allow accrual to the Black/African American and Hispanic/Latinx cohorts to increase, proportionate to the patients already enrolled in the study.

When does the temporary enrollment pause go into effect? When will it end?

The enrollment pause to the “all other race and ethnicity” cohort went into effect on March 1, 2022. Pending periodic review of the study’s enrollment during this time, **accrual into all study cohorts is expected to resume once the Black/African American and Hispanic/Latinx cohorts have reached 75% of their recruitment goals.**

What benefits are expected from the temporary enrollment pause?

The enrollment pause is expected to ensure that the study findings are generalizable to all races and ethnicities. This is achieved through proportionate representation and contemporaneous patient recruitment across socio-demographic and geographic populations throughout the duration of the study.

How will the temporary enrollment pause impact registration of patients at my practice?

Starting March 1, 2022, 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 accrual goals. The application will automatically block 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.

What if I consented a patient who self-identifies into the “all other race and ethnicity” cohort before March 1, but did not register them before the enrollment pause went into effect?

Active dementia practices should be sure to promptly register any patients who have provided consent before March 1, 2022. Patients must be registered in the New IDEAS database to be considered active study participants in New IDEAS. Patients who self-identify into the ‘all other race and ethnicity’ cohort will not be able to be registered in the study portal effective March 1, 2022, even if consent was provided before then. Those patients will still be able to participate in the study once the enrollment pause is lifted. Patients in this situation will have to be re-consented and registered once accrual to all cohorts is re-opened.

What if a patient needs to be re-registered because of scheduling difficulties with the PET facility or other reason?

Re-registration of patients after the enrollment pause begins will be allowed, only if the original registration occurred prior to March 1, 2022. If a patient needs to be re-registered, the dementia practice should contact the New IDEAS Operations Team (newideas@acr.org) to request a re-registration waiver.

What is the most appropriate way to determine someone’s race and ethnicity?

Ask the patient directly. Most electronic medical records will document a patient’s race and ethnicity; however, study guidance is to have the patient self-report their race and ethnicity using the standard options provided by the study on the [Case Registration Form](#). Any racial and ethnic combination that includes at least one of the protocol defined under-represented minority populations will be permitted to continue registration into the study during the temporary enrollment pause.

I am concerned about my practice's ability to recruit underrepresented populations for the New IDEAS Study. Who should I contact?

All dementia practices are highly encouraged to communicate with the New IDEAS Recruitment and Engagement Team (newideas_recruitment@vumc.org) to discuss your practice’s barriers to recruitment in the Black/African American and Hispanic/Latinx cohorts. If you are unable to continue enrolling participants into the New IDEAS Study during the temporary enrollment pause, the Recruitment and Engagement Team is available to provide recruitment training and additional ways to engage with your community.

What recruitment resources are currently available to aid in recruitment of underrepresented populations at my practice?

The New IDEAS Recruitment and Engagement Team designed a comprehensive Recruitment Toolkit to aid in recruitment of underrepresented populations. You can find the full list of Advarra IRB-approved materials on the Recruitment Toolkit under section [IRB Approved Recruitment Materials](#).

I am interested in learning more about the educational and training opportunities regarding recruitment and retention of underrepresented populations in my practice. Where can I find more information?

The New IDEAS Recruitment and Engagement Team has compiled a list of trainings geared toward recruitment and retention of underrepresented populations in research. You can find the full list of resources in the Recruitment Toolkit under section [Educational and Training Materials](#).

What is the New IDEAS Study currently doing to increase enrollment of Black/African American and Hispanic/Latinx patients across the country?

The New IDEAS Recruitment and Engagement team has trained volunteer Study Champions to serve as community-engagement experts for on-the-ground recruitment efforts across the country. 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.

Additionally, the launch of the [Coinsurance Reimbursement Program](#), which minimizes a patient's financial obligations associated with the study, is expected to increase broad participation of historically underrepresented patients across the country and increase the generalizability of the study's findings.

I am interested in becoming a Study Champion for the New IDEAS Study. Who should I contact to learn more information?

Study Champion criteria:

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.

For more information on becoming a Study Champion, please email andrea_mendoza@med.unc.edu and/or tammyjac@email.unc.edu.

I have additional questions about the temporary enrollment pause memo. Who should I contact?

Please direct any memo-related or Portal-related questions or concerns you may have to the New IDEAS Operations Team at newideas@acr.org