

Memorandum

To: All Participating Dementia Practices From: New IDEAS Study Leadership

Date: August 19, 2022

Subject: Temporary Enrollment Pause to "All Other Race/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. 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 with an anticipated reopening of enrollment on September 1, 2022.

As of August 18, 2022, the study's enrollment into the defined race and ethnicity cohorts is:

588 - Black / African American (29.4% of minimum accrual to this cohort; start of pause = 11.8%)

552 - Hispanic / Latinx (27.6% of minimum accrual to this cohort; start of pause = 11.7%)

2,463 - All other races and ethnicities (82.1% of maximum accrual to this 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. 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.

The extension of the enrollment pause will allow for the study team to maximize recruitment efforts of underrepresented patients and collaborate more closely with practices committed to the mission of New IDEAS. Site staff members are encouraged to work with the New IDEAS Recruitment Support Team (newideas_recruitment@vumc.org) to evaluate how they can improve their current recruitment efforts and utilize the study website's Recruitment Toolkit to achieve the nation-wide goals for enrollment. Additional efforts lead by study leadership to increase the enrollment of study participants include providing transportation assistance to PET scan visits as well as additional education and training opportunities for the study's dedicated sites.

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. During the pause, study leadership will report on the periodic evaluation and progress towards reaching the study's pre-specified recruitment goals. For assistance with conversations with patients who are interested in participating but may not be able to enroll at this time, please refer to the <u>FAQ document</u> provided on the study website.

Pursuant to the <u>New IDEAS Enrollment Cap Policy</u> 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 subgroups) with immediate effect."

Study leadership commends the active dementia practices for their continued enthusiasm and commitment to the New IDEAS Study and its mission to address additional gaps in knowledge to advance the study and care of diverse groups of people with Alzheimer's disease. All questions related to this memo should be directed to the study's operational team at newideas@acr.org.



