

## Memorandum

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

Date: February 1, 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. To ensure needed research representation of underrepresented populations, the New IDEAS Study protocol pre-specified that "the study will enroll at least 2,000 Blacks/African Americans, at least 2,000 Latinx/Hispanics, and up to 3,000 additional participants from other racial and ethnic backgrounds."

As of the date of this memo, the study's enrollment into the defined race and ethnicity cohorts is:

223 - Black / African American (11.2% of minimum accrual to this cohort)

174 - Hispanic / Latinx (8.7% of minimum accrual to this cohort)

1,892 - All other races and ethnicities (63.1% of maximum accrual to this cohort)

Effective March 1, 2022, the New IDEAS Study will implement a temporary enrollment pause for the participant cohort representing the 3,000 patients from other racial and ethnic categories. A temporary enrollment pause of the study's fastest accruing cohort will allow for the distribution of enrollment in all study cohorts to even out, so that the study can collect contemporaneous data across cohorts and ensure study generalizability through proportionate representation across socio-demographic and geographic populations. Effective 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 goals. The study anticipates reopening enrollment into all study cohorts on September 1, 2022. The exact timing, however, will depend on the results of periodic evaluation of the progress towards the accrual goals of the Black/African American and Hispanic/Latinx cohorts. During the pause, study leadership will report on the periodic evaluation and progress.

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."

All dementia practices are highly encouraged to communicate with the New IDEAS Recruitment Support Team (<a href="mailto:newideas\_recruitment@vumc.org">newideas\_recruitment@vumc.org</a>) to better understand how to increase minority recruitment activity at your practice. Additional resources and recruitment materials can be downloaded from the study website's <a href="mailto:newidea">Necruitment Toolkit</a> page.

For assistance with conversations with patients who are interested in participating but may not be able to be enroll at this time, please refer to the <u>FAQ document</u> provided on the study website.

Study leadership commends the active dementia practices for their enrollment success into the "all other races and ethnicities" patient cohort and for their continued enthusiasm and commitment to the New IDEAS Study. All questions related to this memo should be directed to the study's operational team at newideas@acr.org.



