

## *Clinical Research in Low-Literacy Populations: Using Teach-Back to Assess Comprehension of Informed Consent and Privacy Information*

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**Table 1. Participant Characteristics (N = 373)**

<i>Characteristic</i>	
Age, mean (SD) years	64.0 (10.4)
Female, No. (%)	204 (54.7)
Race/Ethnicity, No. (%)	
African American (non-Hispanic)	337 (90.3)
Caucasian	28 (7.5)
Hispanic/Latino	4 (1.1)
Asian	3 (0.8)
Other	1 (0.3)
Years of education, mean (SD)	10.9 (3.2)
REALM <sup>a</sup> , No. (%)	
≤3rd grade	78 (20.9)
4th–6th grade	92 (24.7)
7th–8th grade	114 (30.6)
≥9th grade	89 (23.9)
MMSE <sup>b</sup> , mean (SD)	24.6 (3.2)

a. REALM = Rapid Estimate of Adult Literacy in Medicine.

b. MMSE = Mini-Mental State Exam.

**Table 2. Patients' Ability to Teach-Back Consent and HIPAA Content**

	<i>Correct on First Attempt, N (%)</i>
Consent – Purpose	303 (81.2)
Consent – Follow-Up Interview	321 (86.1)
Consent – Randomization	213 (57.1)
Consent – Risks	342 (91.7)
Consent – Benefits	335 (89.8)
HIPAA – Information Collected	312 (83.6)
HIPAA – Confidentiality	256 (68.6)
HIPAA – Withdrawal Options	345 (92.5)
Aggregate Consent – HIPAA Score (all questions) <sup>a</sup>	145 (38.9)

a. Represents being able to teach-back correctly all eight items on the first attempt.

**Table 3. Association of Patient Characteristics with Ability To Teach-Back All Consent and HIPAA Information on First Attempt**

<i>Variable<sup>a</sup></i>	<i>Univariate Analyses Unadjusted OR (95% CI)<sup>b</sup></i>	<i>Multivariable Model Adjusted OR (95% CI)<sup>b</sup></i>
Age, y	0.960 (0.940–0.981)	0.974 (0.951–0.997)
Female gender	1.131 (0.744–1.719)	— <sup>c</sup>
African American race	0.472 (0.236–0.944)	— <sup>c</sup>
Years of education	1.193 (1.105–1.288)	— <sup>c</sup>
MMSE	1.229 (1.143–1.322)	1.098 (0.998–1.207)
Literacy level		
4th–6th grade	2.667 (1.280–5.555)	2.259 (1.048–4.869)
7th–8th grade	3.382 (1.674–6.834)	2.275 (1.049–4.935)
≥9th grade	7.714 (3.711–16.036)	4.344 (1.814–10.404)

a. Age, years of education, and MMSE are continuous variables. Literacy is categorical with ≤3rd grade as the reference group.

b. 95% CI = 95% Confidence Interval; ranges not inclusive of 1 are statistically significant at a level of  $p < 0.05$ .

c. — Indicates variable was dropped during model reduction.