

WEB BASED ADDENDUM

See text for abbreviations

Table A Enrollment/Evaluation Protocol

Pre-Enrollment	
Consent to review medical records	LSRC
Initiate entry survey form	LSRC
Confirmation of subject's capacity to provide consent	Site Director
Phase I	
Consent process completed	LSRC
Standard physical and neurological assessment	Site Director
Review of medical records	LSRC
Medication history form	LSRC
Family history form	LSRC
Modified Hachinski Ischemia Scale	Site Director
Geriatric Depression Scale	LSRC
Inclusion/exclusion criteria met	Site Director
Laboratory studies or MRI scan to be obtained if not available	LSRC
Semi-structured CDR interview with informant and subject	LSRC or Site Director
Subject's CDR score and diagnosis established after review of all Phase I data	Site Director
CDR score and diagnosis confirmed (consensus conference as needed)	Bachman or Mintzer
Phase II	
Neuropsychological battery	CRC
Functional assessment scales	CRC
Collection of biological materials	LSRC
Life style/risk factor form	LSRC
Diet history form	LSRC
Neuroimaging studies	LSRC
Follow-up	
Phone call- follow up every 4 months	LSRC
Annual Re-Assessment	
Updated medical history	LSRC
Medical and neurological assessment	Site Director
Diet history	LSRC
Geriatric Depression Scale	LSRC
Mini Mental State Exam	LSRC
Neuropsychological battery	CRC
Functional assessment scales	CRC
Semi structured CDR interview with informant and subject	LSRC or Site Director
Collection of biological materials	LSR

Table B Description of Standard Clinical Assessment

Demographic Information
Demographic information and other information collected to establish subjects' research diagnosis and includes residential status, education, occupation, age, gender, ethnicity, and marital status.
Medical and Neurological Information
This assessment includes medical information about the estimated time of disease onset, tempo of disease progression, nature of early and current symptoms, presence and/or absence of complete medical and neurology exams, history of prior diagnostic studies, toxin or alcohol exposure, and comprehensive medication history of prescription, over-the-counter medications, herbal medications & vitamins taken within the last 12 months.
Family History
The familial history, especially for first degree relatives, is assessed for dementia, AD, stroke, Parkinson's disease, and other cardiovascular diseases.
Standard Physical and Neurological Examination
The exam includes a general medical exam, vital signs, height, weight, blood pressure (orthostatic), waist circumference, hip circumference, brief sight examination, cranial nerve exam, motor tone and strength, sensation, deep tendon reflexes, tremor, Parkinsonism or other abnormal movements, and gait.
Clinical Dementia Rating Scale (CDR)
The CDR is a well-established, reliable and valid diagnostic and staging measure for dementia of the Alzheimer type based on training and reliability studies in multi-center trials (ref). This measure is widely used in longitudinal and clinical studies to gauge AD progression. When compared to a neurologist using the DSM-III-R to determine if dementia was present, a CDR score of >1 had a sensitivity of 92% and a specificity of 94%. ^(ref) The CDR is a semi-structured interview administered to both patient and informant. Impairment levels are determined in six cognitive-functional categories. The current version and scoring rules are established and now include a semi-structured interview to be used with the Scoring Table. ⁵² The CDR was the primary instrument utilized for determining control, MCI or dementia status and was videotaped for the purpose of confirming the diagnosis. CDR scoring follows the standard set by Washington University.
Mini Mental State Examination (MMSE)
The current guidelines require an objective psychometric assessment to establish the diagnosis of dementia. Although a number of options are available, the MMSE was selected. The MMSE ⁵³ is the most widely used, brief mental status exam in the world. Although it has a number of limitations, it has been used in a variety of research and clinical settings. The MMSE was selected given the familiarity of the sites with the scale and the well-established psychometric properties of the instrument.
Evaluation of Depression
Depression was assessed using the clinical criteria established by the APA Diagnostic and Statistical Manual IVth edition revised (DSM-IV-R) The Site Director or LSRC will also administer the Geriatric Depression Scale (GDS) ⁵⁴ as required by UDS. Subjects meeting criteria for major depressive disorder by DSM-IV criteria as determined by the Site Director were excluded from inclusion in the ADCC and were reassessed after successful treatment. The GDS score was used as a reference for the Site Director but was not the determining factor in assessing the presence or absence of major depression.
Modified Hachinski Ischemia Scale (mHIS)
As modified by Rosen et al., ⁵⁵ the mHIS has good sensitivity at identifying patients with vascular dementia in autopsy studies. ⁵⁶ The mHIS was not be used as a diagnostic measure but as reference information for the local Site Director.
Laboratory Studies
Laboratory studies were obtained consistent with the recommendations of the evidenced based review of the American Academy of Neurology ⁵⁷ . They included TSH; metabolic battery to include AST, ALT, BUN, Cr, electrolytes; and B12/folate. In most cases, laboratory studies were already available for dementia cases and many MCI cases. When laboratory data were not available (or is more than 1 year old) updated laboratory studies are obtained.
Logical Memory IIA (WMSR)
This is a measure of delayed recall (episodic memory) of a story read to the subject at the beginning of the memory testing. The primary measure of performance is the number of story units recalled. The scoring is adjusted for level of education. The specific cutoff score for the WMS-R ⁵⁸ was taken from the ADNI in order to differentiate amnesic MCI from non-amnesic MCI.
Neuroimaging for Diagnostic Purposes
Existing neuroimaging studies obtained by a clinician to confirm a clinical diagnosis of AD, were used for research diagnostic purposes. Although imaging studies were available on almost all dementia cases, they were rarely available for MCI or control cases.

Table C Subject characteristics by race

	Control		AD		MCI	
	Black	White	Black	White	Black	White
	31(77.5%)	9(22.5%)	23(67.6%)	11(32.3%)	15(57.6%)	11(42.3%)
Gender						
Male	11(35.4%)	5(55.5%)	6(26.0%)	7(63.6%)	8(53.3%)	3(27.2%)
Female	20(64.5%)	4(44.4%)	17(73.9%)	4(36.3%)	7(46.6%)	8(72.7%)
Age						
<64	6(19.3%)	3(33.3%)	2(8.7%)	0(0.0%)	2(13.3%)	2(18.1%)
65-74	19(61.2%)	3(33.3%)	4(17.3%)	6(54.5%)	9(60.0%)	4(36.3%)
75-84	5(16.1%)	1(11.1%)	13(56.5%)	4(36.3%)	3(20.0%)	5(45.4%)
85+	1(3.2%)	2(22.2%)	4(17.3%)	1(9.0%)	1(6.6%)	0(0.0%)
Living status						
Alone	10(32.2%)	2(22.2%)	1(4.3%)	1(9.0%)	2(13.3%)	2(18.1%)
Assisted	21(67.7%)	7(77.7%)	22(95.6%)	10(90.9%)	13(86.6%)	9(81.8%)
Residence status						
Home	30(96.7%)	8(88.8%)	23(100.0%)	11(100.0%)	15(100.0%)	9(81.8%)
Facility	1(3.2%)	1(11.1%)	0(0.0%)	0(0.0%)	0(0.0%)	2(18.1%)
Clinic location						
MUSC/VA	12(38.7%)	3(33.3%)	9(39.1%)	4(36.3%)	9(60.0%)	5(45.4%)
Other	19(61.2%)	6(66.6%)	14(60.8%)	7(63.6%)	6(40.0%)	6(54.5%)
Marital Status						
Married	16(51.6%)	6(66.6%)	8(34.7%)	10(90.9%)	10(66.6%)	7(63.6%)
Unmarried	15(48.3%)	3(33.3%)	*15(65.2%)	1(9.0%)	5(33.3%)	4(36.3%)
Environment						
Rural	13(41.9%)	5(55.5%)	16(69.5%)	5(45.4%)	7(46.6%)	5(45.4%)
City	17(54.8%)	4(44.4%)	5(21.7%)	5(45.4%)	6(40.0%)	5(45.4%)
Other	1(3.2%)	0(0.0%)	2(8.7%)	1(9.0%)	2(13.3%)	1(9.0%)
	Median	Median	Median	Median	Median	Median
Age	70.0	66.0	78.0	74.0	70.0	73.0
Education	13.0	15.0	*11.0	12.0	13.0	14.0
CDR Score	0.0	0.0	2.0	2.0	0.5	0.5
Sum of Boxes	0.0	0.0	9.0	6.5	1.0	1.5

* denotes a difference between AA and whites at $p < .01$