REGARDS COGNITIVE ASSESSMENT DATA MANUAL – DRAFT

I. Overview of REGARDS Cognitive Assessment Approach

Rationale

The REGARDS cognitive assessment was designed to be: 1) sensitive to Vascular Cognitive Impairment (VCI), 2) consistent with the goals of the NINDS-CSN VCI Harmonization Standards[1], 3) brief (gathered in under 15 minutes), and 4) amenable to telephone administration using customized technology. We sought to add to our existing assessment protocol in order to capitalize on the rich longitudinal data already gathered and improve our sensitivity to VCI. The measures chosen can be combined to form composite indices representing cognitive domains affected by VCI.

REGARDS Cognitive Functioning Outcomes

The cognitive assessments being performed fall into two groups:

- The Six-item Screener (SIS) provides a screening assessment of global cognitive function. It results in a dichotomous outcome (impaired versus not impaired).

    o SIS, beginning December 2003, administered at annual intervals

- The short battery includes domains of cognitive function assessed on continuous scales; additional participant burden in collection necessitates less frequent data collection.

    o CERAD Word List Learning (WLL) and Delay Recall (WLD), beginning Jan. 2006 at 18-mo. intervals, changed to 2-yr. intervals in Feb. 2008

    o Semantic (Animal) Fluency (AFT), beginning Jan. 2006 at 18-mo. intervals on different follow-up schedule than WLL and WLD, changed to 2-yr. intervals and on same follow-up schedule in Feb. 2008

    o Phonemic (Letter F) Fluency, beginning Feb 2008, added to short battery (2-yr. intervals) (part of NINDS 5-min. battery)

- o MoCA registration, recall, orientation piloted 4/7/08-4/3108,, added to short battery (2-yr. intervals) in Mar. 2009? (part of NINDS 5-min. battery)

- Other

  - o 4-item CES-D depressive symptom screener was given at baseline in conjunction with SIS; was added to short battery in Mar. 2009 (2 yr. intervals)

The WLL, WLD, AFT, and NINDS 5-minute battery tests are now administered as a unit at months 18, 42, 66, 90, and 114.

	Measure	Score	Occasions of Measurement
Global Cognitive Status	Six-item Screener	Number correct (0-6) Dichotomous categorization (intact, impaired)	Measured on an annual basis (months 12, 24, 36 …)
Short Battery Cognitive Domains			
Learning	Word List Learning (WLL)	Sum of 3 learning trials (0-30)	Measured on a bi-annual basis starting with month 18 (months 18, 42, 66, 90, 114)
	NINDS 5-item Registration	Number correct (0-5)	
Memory	Word List Delayed Recall (WLD)	Number correct (0-10)	
	NINDS 5-item Recall	Number correct (0-5)	
	NINDS Orientation	Number correct (0-6)	
Executive	Animal Fluency	Number correct in 60 seconds, Number of intrusions	
	NINDS Letter Fluency	Number correct in 60 seconds, Number of intrusions	
Overall Cognitive Composite (Short Battery)	WLL + WLD + Animal Fluency + NINDS Registration + NINDS Orientation + NINDS Recall + NINDS Letter Fluency	z-transformed composite of domain scores	

For global cognitive status using the Six-item Screener (SIS), cognitive impairment is defined as a score of 4 or fewer correct; incident cognitive impairment is defined as a change from intact (scores of 5 and 6) to impaired (scores of 4 or fewer) at the last available assessment (augmented by sensitivity analysis—score in impaired range at last two assessments).

Regression-based approaches may be used to define cognitive impairment on the short battery. First, associations between demographic factors and cognitive test performance within the study cohort will be determined separately for each cognitive test, domain, and composite, via multivariable linear regression. Demographic factors (age, education, gender, race, region) will be regressed on scores to develop a predicted score for each person. When an actual score is 1.5 SD or more below the individual's predicted score, that test, domain, or composite will be defined as impaired.

Approaches to characterizing meaningful cognitive decline within the continuous measures are being discussed (Standard Error of Measurement, Reliable Change Index, Regression-based deviations, Quartiles, Proportion of low test scores).

      a. SEM - formula from Dudek 1979, where $SEM = SD_{test} (1 - r_{test\text{-}retest}^2)^{1/2}$. ACTIVE defined 1 unit change as significant. Number of S's with $\geq$ 1 SEM decline on a continuous variable test could be defined as decliners. The cut-point (1 SEM) is arbitrary; it includes the range within which 2/3rd of S's who did not change should fall (based on precision of the instrument). Test-retest correlation is accounted for, thus change is "meaningful." Could use 2 SEM criterion to be more conservative.

b. RCI from Jacobson and Truax 1991, where $RCI = X_2 - X_1/SE_{difference}$; $SE_{diff} =$ $[2(SEM)^2]^{1/2}$. This is then multiplied by 1.96 to give the RCI interval. It compares roughly to 2 SEM above.

c. Proportions or counts of low test scores – Among available tests, a predefined number or proportion of scores below a certain threshold (-1.0, -1.5, or -2.0 SD, depending on desire for stringency) may be designated as constituting a "case" of cognitive impairment, or incident impairment if the "case" was previously intact.

d. Regression-based deviation scores (deviation from expected decline). Cognitive change will be determined by calculating the average rate of change in available cognitive tests and composites using mixed model approaches (Laird & Ware) to fit random effects regression models based on the slope of the line fitting all available cognitive results from baseline and follow-up, adjusted for age, race, gender, years of education, and in some cases region of residence (Participants' data may be censored at the time of a stroke, TIA, death, or study dropout.)

e. Quartiles or quintiles - segment performance into bands based on score distribution.

Approaches a, b, and c are suitable when the design calls for defining "cases." Approaches c and d are suitable for data-driven generation of continuous score trajectories over time as a function of a given variable or set of variables.

II. Measures

Six-item Screener

The Six-item Screener (SIS)[2] is administered by telephone in REGARDS. It consists of 3-item recall and 3-item temporal orientation. For telephone administration, we modified the instructions for 3-item recall to include "please do not write anything down," and for the orientation items, we modified the instruction by prefacing each item with the phrase, "Without looking at a calendar or a watch, what [year/month/day of the week] is this?"

The SIS was performed during baseline telephone interviews beginning in December, 2003 (11 months after enrollment began) and during the follow-up period on an annual basis. Incident cognitive impairment is defined as a shift from intact cognitive screening status (score of 5 or 6 correct) at the participant's first SIS assessment (whether it occurred at baseline or a follow-up visit) to impaired cognitive screening status (a score of 4 or fewer correct) at the latest available assessment. The SIS has been validated in both community and clinical samples and among both black and white adults. Its sensitivity and specificity to clinical diagnoses of dementia and mild cognitive impairment are 74% and 80% respectively for both groups combined versus cognitively normal elders)[2]

Word List Learning and Delayed Recall

Word List Learning and Delayed Recall, from the Consortium to Establish a Registry for Alzheimer's Disease (CERAD) battery[2], are telephone administered in REGARDS. These measures were first incorporated into the REGARDS follow-up telephone interviews in Jan. 2006 during assessments occurring at 18-mo. intervals. The frequency of assessment was

changed to 2-yr. intervals in Feb. 2008. Word List Learning (WLL) and Delayed Recall (WLD)

are usually treated as separate assessments, representing the cognitve domains of learning and

memory respectively.The list learning portion consists of three learning trials of a list of 10

semantically-unrelated words which are presented in a fixed order that varies across the three

trials[3], followed by a free recall trial after a 5-minute delay filled with non-cognitive interview

questions. In REGARDS, this measure is administered according to the standard protocol, with

two modifications for telephone administration: (1) no visual presentation of the stimuli and (2)

participants are instructed not to write anything down. In addition, a recognition trial is not

administered in REGARDS. The instructions for each learning trial, including the oral

presentations of the word list, are administered via a recording so that all participants are

exposed to the same narration, thereby avoiding any differences in dialect, tone, gender, or

volume that might affect participants' performance. For list learning, the score from the three

trials are summed, yielding a score ranging from 0-30, after excluding repetitions (repeating the

same word more than once) and intrusions (including a word not on the list). For delayed recall,

participants are asked to freely recall as many of the ten words as possible after the 5-minute

delay during which non-cognitive interview questions are asked. Scores range from 0 to 10 after

excluding repetitions and exclusions.

Because telephone administration of these measures is associated with the opportunity for non-

standard behavior among participants (such as writing down the lists despite the instruction not

to do so), we developed a procedure for flagging performance patterns that are statistically and

conceptually unlikely to occur by chance. Specifically, the score of any participant who

responds to a learning trial with all 10 words, in the exact order presented on that trial or a prior

trial, is flagged. In addition, the score of any participant whose score on the Delayed Recall trial is 3 or more points higher than their score on any learning trial is flagged (e.g., maximum of 7 on one of three learning trials, and score of 10 on the delayed recall trial). The CFWG discussed and approved this procedure. In data analyses, participants with non-standard performance patterns may be excluded, or an indicator for suspect performance profiles may be used as a covariate in analyses. Of note, < 2% of REGARDS participants show these non-standard patterns.

Note also that the order of words recalled is captured in the learning trials and the recall trial, providing the opportunity for secondary analyses of primacy and recency effects, etc.

Semantic and Phonemic Fluency

The Semantic (Animal) Fluency Test (AFT) was first implemented into follow-up telephone interviews in Jan. 2006 and subsequently at 18-mo. intervals on a different follow-up schedule than WLL and WLD. The interval was changed to 2-yr. intervals and on the same follow-up schedule as WLL and WLD in Feb. 2008. Phonemic (Letter F) Fluency was first implemented into follow-up interviews in Feb 2008 and currently is administered at 2-yr. intervals concurrently with WLL, WLD, AFT, and the remainder of the short battery. The fluency measures are administered according to standardized scripts[4] which require participants to name as many words as they can beginning with the letter 'F', and subsequently, to name as many animals as they can. The time allotted for each measure is 1 minute. Raw scores on each consist of the total number of valid responses produced by each participant in 60 seconds, after subtracting repetition and intrusion errors.

The assessments are recorded in WAV files at the time of survey and then played back later for scoring by trained college-educated scorers, following written scoring protocols, facilitated by computer-assisted scoring programs developed for REGARDS. These programs capture several variables beyond raw total scores that may be used as secondary indices of processing speed and executive function (i.e., number of intrusion errors, number of words produced in 15-sec. increments, order of responses for inspection of clustering strategies and switching frequency, etc.). Ongoing quality control efforts consist of evaluating scorers' agreement with an expert scorer. Inter-scorer agreement is excellent (kappas exceed .95)

NINDS/CSN 5-minute Battery

The NINDS/CSN 5-minute Battery was recommended by the National Institute of Neurological Disorders and Stroke-Canadian Stroke Network Vascular Cognitive Impairment Harmonization Standards[1] for use in studies calling for very brief assessments, epidemiological studies, and/or telephone administration. The 5-minute battery consists of selected subtests of the Montreal Cognitive Assessment (MoCA)[5] : 5-word delayed memory recall, 6-item orientation, and 1-letter [F] phonemic fluency). MoCA registration, recall, and orientation were implemented into the REGARDS short battery follow-up assessments beginning in Mar. 2009 at 2-yr. intervals. Prior to adding these items to the short battery, a pilot study was conducted among 200 REGARDS participants to determine whether interference would occur between the MoCA recall list and the Word List Learning and Delayed Recall lists if these assessments were administered on the same telephone call, albeit separated in time by ~20 minutes. One hundred participants were given the MoCA items in conjunction with the previously implemented short battery, and 100 participants

were given the MoCA items on a separate phone call 1 to 3 days after the first. There was no difference in recall performance due to timing; therefore, the items were added to the short battery and administered as a unit on scheduled follow-up calls.

For telephone administration, the spatial orientation items (place and city) were modified such that the participant is asked his or her street address and city (confirmed by the interviewer via a pre-populated field in the computer script).

The MoCA was developed as an alternative to the Mini-Mental State Examination (MMSE)[6]. The MoCA was specifically designed to detect individuals with mild cognitive impairment (MCI), who may score within the normal range on the MMSE. The 5-minute battery used in REGARDS was specifically chosen to be sensitive to the deficits commonly seen in vascular cognitive impairment (VCI).

As scoring standards have not been published for the NINDS 5-minute battery, two approaches may be used for calculating summary scores. For the first (which more likely reflects what will occur in clinical practice), the scoring procedures and cutpoints recommended for the MoCA items constituting the 5-minute battery (http://www.mocatest.org) may be used to generate a summary value for the 5-minute battery. This yields scores ranging from 0 to 12, with lower scores indicating greater impairment. In the second (which more likely reflects what will occur in the research setting), the 3 individual items on the 5-minute battery - memory recall, orientation, and phonemic fluency may be converted to Z-scores and summed to give a continuous measure of performance.

Also note that MoCA Registration of the 5-word recall list is not scored per the MoCA protocol. However, performance on this variable is captured in our database, and Registration may be used in forming the Learning composite variable as indicated in the Overview section of this manual.

CES-D-4

The Center for Epidemiological Studies-Depression—4-item version (CES-D-4)[7] was used to evaluate depressive symptoms and is considered a key covariate in the interpretation of cognitive performance scores. This measure was derived from the full CES-D, and scores correlate acceptably with the full and 8-item CES-D measures.[7] It was administered in the baseline CATI interview and was implemented into the REGARDS short cognitive battery follow-up assessments beginning in Mar. 2009 at 2-yr. intervals.

Each of the 4 items in this instrument is assigned one value of 0, 1, 2 or 3. "Rarely or none of the time (less than 1 day)" = 0; "Some or a little of the time (1-2 days)" = 1; "Occasionally or a more moderate amount of the time (3-4 days)" = 2; "More or all of the time (5-7 days)" = 3. Total scores range from 0 to 12; a score $\geq$ 4 suggests a clinically significant level of psychological distress. This does not necessarily mean that the participant has a clinical diagnosis of depression. In a general population, about 20% would be expected to score in this range.

We are careful in REGARDS to refer to CES-D-4 scores as levels of "depressive symptoms" rather than "depression."

III. References

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2. Callahan CM, Unverzagt FW, Hui SL, Perkins AJ, Hendrie HC. Six-item Screener to identify cognitive impairment among potential subjects for clinical research. *Med Care.* 2002;40:771–781.

3. Morris, J.C., et al., The Consortium to Establish a Registry for Alzheimer's Disease (CERAD). Part I. Clinical and neuropsychological assessment of Alzheimer's disease. *Neurology* 1989; 39(9):1159-65.

4. Strauss, E., E. Sherman, and O. Spreen, *A compendium of neuropsychological tests*. 3rd ed. 2006, New York: Oxford University Press.

5. Nasreddine ZS, Phillips NA, Bedirian V, Charbonneau S, Whitehead V, Collin I, Cummings JL, Chertow H. The Montreal Cognitive Assessment, MoCA: a brief screening tool for mild cognitive impairment. J Am Geriatr Soc 2005; 53: 695-699.

6. Folstein M, Folstein S, McHugh P. Mini-mental state: A practical method for grading the cognitive state of patients for the clinician. *Journal of Psychiatric Research.* 1975;12:189-198.

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IV. Data Descriptions

Six-item Screener Data Description:

Incident impairment is typically a score <= 4 at the most recent follow-up visit, as per the decision of the REGARDS Cognitive Function Working Group (CFWG). For analyses of incident impairment, participants with a first SIS score in the impaired range (<=4) are excluded. Although analyses of incident impairment have focused on the most recently observed SIS score, sensitivity analyses requiring impairment at the last two assessments has also been recommended by the REGARDS CFWG. Additionally, the CFWG recommends censoring the scores at incident stroke (i.e do not use any scores from assessments that occurred after the participant's first incident stroke). SAS code for censoring at incident stroke is provided below. Alternatively, one could use all of the SIS assessments, and include an indicator of incident stroke (as a covariate) for those with stroke occurring between the first and last assessments. Note that alternate word lists for the 3-item recall component of the SIS are administered every other year. We have found that participants tend to perform better on one list compared to the other. However, on average, this should not affect results, and models that account for differences in word list have not had different results than those that do not. Therefore, we generally ignore this minor performance difference and do not include form type (original or alternate) as a variable in analyses.

Common exclusions: Impairment at first SIS (delete cogscore1<=4), reported stroke at baseline (delete stroke_sr = 'Y'), incident stroke before first assessment (delete incident_stroke=1), only one assessment (delete only_assessment=1).

Cognitive_SIS dataset PROC CONTENTS + Comments

Label	Variable
ID number	id_num
Date of first SIS score, whether baseline or follow-up interview.	cogdate1
	cogdate2
	cogdate3
	cogdate4
	cogdate5
	cogdate6
	cogdate7
	cogdate8
	cogdate9
First SIS score, whether baseline or follow-up interview.	cogscore1
	cogscore2
	cogscore3
	cogscore4
	cogscore5
	cogscore6
	cogscore7
	cogscore8
	cogscore9
The total number of assessments	total_assess
CATI interview date	INTDATE
Time between the most recent assessment and the baseline intdate	assess_interval
	stroke_date1
	stroke_date2
	stroke_date3
Indicator is 1 if last SIS score was 4 or less.	incident_impairment
Indicator is 1 if last two SIS scores were both 4 or less.	incident_impairment2
First adjudicated incident stroke(yes=1/no=0)	stroke1
Second adjudicated incident stroke(yes=1/no=0)	stroke2
Third adjudicated incident strokre(yes=1/no=0)	stroke3
Should be excluded due to baseline self reported stroke	stroke_SR
Should be excluded due to baseline impairment. Indicator is 1 if first SIS score was 4 or less.	Baseline_impair
Should be excluded due to incident stroke prior to first assessment. This is different from baseline reported stroke. Also this does not say anything about whether a stroke occurred after first SIS score.	incident_stroke

Should be excluded due to only had 1 assessment	only_assessment

```sas
*This code can be used to censor SIS data at the first incident stroke (be
sure to also do exclusions for baseline stroke and incident stroke that
occurred before first SIS (see data description for these variables);

*Need a long version of SIS dataset;

data sislong;
set cognitive_sis;
array sisset1 (9) cogdate1 - cogdate9;
array sisset2 (9) cogscore1 - cogscore9;
do i=1 to 9;
sisdate=sisset1[i];
sisscore=sisset2[i];
if sisset1[i] ne . then output;
end;
keep id_num i sisdate sisscore stroke_date1;
format sisdate date10.;
run;

*Filter out any dates with missing scores;

data sislong2;
set sislong;
if sisscore=. then delete;
run;

proc sort data=sislong2;
by id_num sisdate;
run;

*Filter out all SIS dates occurring on or
after first stroke date;

data censored;
set sislong2;
if stroke_date1 ne . then do;
if sisdate >= stroke_date1 then delete;
end;
run;

*If you are interested in the last SIS score for defining decline then use
this too;
data censoredlastsis;
set censored;
by id_num sisdate;
if last.id_num;
rename sisdate = lastsisdate
sisscore = lastsisscore;
*exclude individuals with only one assessment (where last assessment is the
first assessment);
if i=1 then delete;
run;
```

Word List Learning and Recall Data Description:

Typically, the outcome from these assessments are the "wll_sum" variable for wordlist learning, or the "wll_delay" variable for delayed recall. In general, the suspected cheaters are excluded (delete cheater=1). Note that these computed variables already take into consideration repetitions and intrusions (i.e., these errors have been subtracted from total scores).

Cognitive_WLL dataset PROC CONTENTS + Comments

Label	Variable
ID number	id_num
Sequence number. Only included assessments with sequence in (3,7,11…).	wll_seqno
Date of wordlist assessment	wll_date
Score from first learning trial. Intrusions and repetitions already removed.	wll_score1
Score from second learning trial. Intrusions and repetitions already removed.	wll_score2
Score from third learning trial. Intrusions and repetitions already removed.	wll_score3
Score from delayed recall trial. Intrusions and repetitions already removed.	wll_delay
Sum of scores for trials 1-3. Use this sum for wordlist learning. Intrusions and repetitions already removed.	wll_sum
Number of intrusions in delayed recall.	intru_delay
Sum of intrusions for three wordlist learning trials.	intru_sum
Sum of repeats for three wordlist learning trials.	repeat_sum
Number of repeats in delayed recall.	repeat_delay
Indicator set to 1 if trouble hearing on any of four trials. All scores set to missing if it occurred during three wordlist learning. Only delayed recall score set to missing if it occurred during delayed recall.	trouble_hearing_ind
Indicator set to 1 if refusal on any of four trials. All scores set to missing if it occurred during three wordlist learning. Only delayed recall score set to missing if it occurred during delayed recall.	refuse_ind
All scores set to missing and indicator set to 1 if no data for any of the four trials.	miss_ind

Indicator set to 1 if suspected of cheating (by performing 3 or more better on recall than on their best learning trial or remembered the words in exact order).	cheater

Semantic and Phonemic Fluency Data Description:

There are two options for analysis for the AFT – the af_t_score (which is normalized with a reference population), and the af_score (which is the final score, removing intrusions and repetitions). In general, **af_score** is the primary variable for analysis. In addition, the date of the assessment is indicated by af_date. The sequence number for the follow-up at which the AFT was performed is af_seqno. The Letter F assessment is structured similarly, with the variables all preceded by LF, rather than AF. In addition, there is no t-score for the Letter F.

Several common errors have occurred in the process of data collection and file retrieval. Thes are indicated in the variables: AF_status/LF_status. "Invalid" indicates data that cannot be used (e.g., interviewer stopped recording too early, equipment failure during data collection, etc.). "No Audio" indicates that no recording was captured, primarily due to equipment failures. "Help" indicates that the participant received help/assistance from someone in their home environment (e.g., a person in the background was calling out categories or specific animal names/letter F words), while "Prompt" indicates that the participant was given a disallowed prompt by the interviewer (e.g., "Think of the zoo"). Files marked with Prompt or Help may be excluded, or they may be used, with indicators for these situations used as covariates in analyses.

In addition, because of the timing of the implementation for the AFT, there are some assessments that were performed off-sequence. These are included in the dataset, but have are indicated with the variable: af_off_seq_ind.

Cognitive_Animnaming dataset PROC CONTENTS + Comments

Label	Variable
ID number	id_num
Sequence number. Only included assessments with sequence in (2,4,6) or (3,7,11…).	af_seqno
Raw number of words between 1 and 15 seconds	af_1_15
Raw number of words between 16 and 30 seconds	af_16_30
Raw number of words between 31 and 45 seconds	af_31_45
Raw number of words between 46 and 60 seconds	af_46_60
Raw total number of words	af_count
Repetitions	af_reps
Intrusions	af_intru
Animal fluency score for analysis. Intrusions and repetitions have been removed.	af_score
Animal fluency t-score. Normalized with a reference population, this is generally NOT the primary score for analysis.	af_t_score
Scores set to missing if status in (No Audio,Invalid,No Audio,Prompt-Invalid). Prompt means the interviewer helped prompt the participant during their answer, etc.	af_status
Date of animal fluency assessment	af_date
This indicator set to 1 if from "old" sequence (2,4,6).	af_off_seq_ind

Cognitive_Letterf dataset PROC CONTENTS + Comments

Label	Variable
ID number	id_num
Sequence number. Only included assessments with sequence in (3,7,11…).	Lf_seqno
Raw number of words between 1 and 15 seconds	Lf_1_15
Raw number of words between 16 and 30 seconds	Lf_16_30
Raw number of words between 31 and 45 seconds	Lf_31_45
Raw number of words between 46 and 60 seconds	Lf_46_60
Raw total number of words	Lf_count
Repetitions	Lf_reps

Simple intrusions	Lf_intru
Special rule violation type of intrusions	Lf_ruleint
Letter fluency score for analysis. All intrusions and repetitions have been removed.	Lf_score
Scores set to missing if status in (No Audio,Invalid,No Audio,Prompt-Invalid). Prompt means the interviewer helped prompt the participant during their answer, etc.	Lf_status
Date of letter fluency assessment	Lf_date

Limitations: Some WAV files were lost in previous years due to drive space limitations at random, interviewer error, and equipment failures. In another technical glitch, the WAV file was mismatched at random to the wrong participant but this effect has been minimized by matching on respondent number in addition to REGARDS ID, and excluding those who did not give permission to record.

NINDS 5-minute Battery Data Description:

To be developed.

MOCA

Label	Variable
ID number	id_num
Sequence number	moca_seqno
Date of MOCA assessment	moca_date
Score from first 5 word list	moca1
Indicator set to 1 if refusal on any of the word lists. MOCA memory score set to missing	moca_refuse
Score from second 5 word list	moca2
Score from todays month/day/year	moca3
Score from day of week	moca4
Score from street address	moca5
Score from city address	moca6
Score from recall of 5 word list	moca7
Sum of scores for orientation items	moca_orientation
Memory score (recall) after trial refusals set to missing	moca_memory
MOCA total score (orientation + memory)	moca_total

CES-D-4 Data Description:

To be developed.