Alzheimer's Disease Neuroimaging Initiative Grand Opportunity ADNI GO

Worksheet Packet

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SCHEDULE OF EVENTS (EMCI SUBJECTS)

Visit Name	Screen	Baseline	Month 3	Month 6	Month 12	Month 18
Visit Type	In-Clinic	In-Clinic	MRI	In-Clinic	In-Clinic	Telephone Check
Explain study	X					
Obtain consent	X					
Demographics, Family History, Inclusion and Exclusion Criteria	X					
Medical History, Physical Exam, Neurological Exam, Hachinski	X					
Vital Signs	X	X		X	X	
Height	X					
Screening Labs	X					
DNA Sample Collection for APOE Genotyping and GWAS		X				
Cell Immortalization Sample Collection		X				
American National Adult Reading Test		X				
Mini Mental State Examination	X			X	X	
Logical Memory I and II	X				X	
Everyday Cognition (ECog)		X		X	X	
Montreal Cognitive Assessment (MoCA)		X		X	X	
Category Fluency (Animals)		X		X	X	
Trails A & B		X		X	X	
Boston Naming Test (30-item)		X		X	X	
Auditory Verbal Learning Test		X		X	X	
Geriatric Depression Scale	X			X	X	
Clock drawing		X		X	X	
Neuropsychiatric Inventory Q		X		X	X	
ADAS-Cog 13 (with Delayed Word Recall and Number Cancellation)		X		X	X	
Clinical Dementia Rating Scale	X			X	X	
Activities of Daily Living (FAQ)		X		X	X	
Plasma and Serum Biomarker Collection		X		X	X	
RNA Sample Collection		X			X	
Concomitant Medications	X	X		X	X	X
Adverse Events	X	X		X	X	X
Diagnostic Summary		X		X	X	
3T MRI Imaging (100%)	X		X*	X	X	
¹⁸ F-AV-45 Amyloid Imaging (100%)		X				
FDG-PET Imaging (100%)		X				
CSF Collection by Lumbar Puncture (LP) (100%)		X				

^{*}Month 3 MRI is timed from Screening MRI

SCHEDULE OF EVENTS (FOLLOW-UP CN AND LMCI SUBJECTS)

Visit name	Baseline	Month 6	Month 12	Month 18
Visit Type	In-Clinic	Telephone Check	In-Clinic	Telephone Check
Explain study	X			
Obtain consent	X			
Medical History, Physical Exam, Neurological Exam	X			
Vital Signs	X		X	
Mini Mental State Examination	X		X	
DNA Sample Collection for GWAS	X			
Logical Memory I and II	X		X	
Everyday Cognition (ECog)	X		X	
Montreal Cognitive Assessment (MoCA)	X		X	
Category Fluency (Animals)	X		X	
Trails A & B	X		X	
Boston Naming Test (30-item)	X		X	
Auditory Verbal Learning Test	X		X	
Geriatric Depression Scale	X		X	
Clock drawing	X		X	
Neuropsychiatric Inventory Q	X		X	
ADAS-Cog 13 (with Delayed Word Recall and Number Cancellation)	X		X	
Clinical Dementia Rating Scale	X		X	
Activities of Daily Living (FAQ)	X		X	
Plasma and Serum Biomarker Collection	X		X	
RNA Sample Collection	X		X	
Concomitant Medications	X	X	X	X
Adverse Events	X	X	X	X
Diagnostic Summary	X		X	
1.5T MRI Imaging (100%)	X		X	
¹⁸ F-AV-45 -Amyloid Imaging (100%)	X			
FDG PET Imaging (100%)	X			
CSF Collection by Lumbar Puncture (LP)	X			

Note: All subjects will be asked if they are willing to consent to at least one LP. Subjects who are not able or willing to have LP, MRI, FDG-PET, or ¹⁸F-AV-45 Amyloid imaging will still be followed for cognitive and clinical assessments.

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Alzhein	ner's Disease Cooperative Study
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	Inclusion Criteria
	Page 1 of 3
	Visit: EMCI Screening
г	ADNI PARTICIPANT NUMBER EXAMINER INITIALS EXAMINATION DATE
	MONTH DAY YEAR
Inst	Indicate whether the following criteria has been met. If the answer to any question is "NO", the participant MAY NOT be enrolled in the study. Contact the Project Director for clarifications on the criteria or any potential protocol deviations.
1.	Subject must have a memory complaint by subject or study partner that is verified by a study partner. \(\sum \) Yes \(\sum \) No
ı	Abnormal memory function documented by scoring below the education adjusted cutoff on the Logical Memory II subscale (Delayed Paragraph Recall) from the Wechsler Memory Scale –Revised (the maximum score is 25): a. 9-11 for 16 or more years of education. b. 5-9 for 8-15 years of education. c. 3-6 for 0-7 years of education. Yes No
	Mini-Mental State Exam score between 24 and 30 (inclusive) (Exceptions may be made for subjects with less than 8 years of education at the discretion of the project director. Yes No
4. (Clinical Dementia Rating = 0.5. Memory Box score must be at least 0.5. Yes No
	General cognition and functional performance sufficiently preserved such that a diagnosis of Alzheimer's disease cannot be made by the site physician at the time of the screening visit. Yes No
6.	 Stability of Permitted Medications for 4 weeks. In particular, subjects may: a. Take stable doses of antidepressants lacking significant anticholinergic side effects (if they are not currently depressed and do not have a history of major depression within the past 1 year). b. Estrogen replacement therapy is permissible. c. Gingko biloba is permissible, but discouraged. d. Washout from psychoactive medication (e.g., excluded antidepressants, neuroleptics, chronic anxiolytics or sedative hypnotics, etc.) for at least 4 weeks prior to screening. e. Cholinesterase inhibitors and memantine are allowable if stable for 12 weeks prior to screen. Yes No

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	Inclusion Criteria					
	Page 2 of 3 Visit: EMCI Screening					
	ADNI PARTICIPANT NUMBER					
7.	Geriatric Depression Scale less than 6.					
	☐ Yes					
	□ No					
8.	Age between 55-90 (inclusive). Tes					
	□ No					
9.	Study partner is available who has frequent contact with the subject (e.g. an average of 10 hours per week or more), and can accompany the subject to all clinic visits for the duration of the protocol. Yes No					
10.	Visual and auditory acuity adequate for neuropsychological testing. ☐ Yes ☐ No					
11.	Good general health with no diseases expected to interfere with the study. Yes No					
12.	Subject is not pregnant, lactating, or of childbearing potential (i.e. women must be two years post-menopausal or surgically sterile). Yes No					
13.	Willing and able to participate in a longitudinal imaging study. ☐ Yes ☐ No					
14.	Hachinski less than or equal to 4. Yes No					
15.	Six grade education or has a good work history (sufficient to exclude mental retardation). Yes No					

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Inclusion Criteria
Page 3 of 3
Visit: EMCI Screening ADNI PARTICIPANT NUMBER
16. Must speak English or Spanish fluently.
☐ Yes
□ No
17. Willing to undergo repeated MRIs (3Tesla) and at least one PET (FDG and Amyloid imaging) and no medical contraindications to MRI.
☐ Yes
□ No
18. Agrees to collection of blood for GWAS, APOE testing and DNA banking.
Yes
□ No
19. Agrees to collection of blood for biomarker testing.
Yes
□ No
20. Agrees to at least one lumbar puncture for the collection of CSF.
Yes
□ No

Version Alzheimer's Disease Cooperative Study
ADOS
Exclusion Criteria
Page 1 of 2
Visit: EMCI Screening
ADNI PARTICIPANT NUMBER EXAMINER INITIALS EXAMINATION DATE
Instructions:
Indicate whether the following criteria has been met. If the answer to any question is "YES", the participant MAY NOT be enrolled in the study. Contact the Project Director for clarifications on the criteria or any protocol deviations.
 Any significant neurologic disease other than suspected incipient Alzheimer's disease, such as Parkinson's disease, multi-infarct dementia, Huntington's disease, normal pressure hydrocephalus, brain tumor, progressive supranuclear palsy, seizure disorder, subdural hematoma, multiple sclerosis, or history of significant head trauma followed by persistent neurologic defaults or known structural brain abnormalities. Yes No
 Screening/baseline MRI scans with evidence of infection, infarction, or other focal lesions. Subjects with multiple lacunes or lacunes in a critical memory structure are excluded. Yes No
 3. Presence of pacemakers, aneurysm clips, artificial heart valves, ear implants, metal fragments or foreign objects in the eyes, skin or body. Yes No
 4. Major depression, bipolar disorder as described in DSM-IV within the past 1 year. Psychotic features, agitation or behavioral problems within the last 3 months which could lead to difficulty complying with the protocol.
5. History of schizophrenia (DSM IV criteria). Yes No
6. History of alcohol or substance abuse or dependence within the past 2 years (DSM IV criteria).

 Any significant systemic illness or unstable medical condition which could lead to difficulty complying with the protocol.
 Yes ☐ No

☐ No

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	Exclusion Criteria Page 2 of 2		
	Visit: EMCI Screening		
	ADNI PARTICIPANT NUMBER		
8.	Clinically significant abnormalities in B12, or TFTs that might interfere with the study. — Yes		
	□ No		
9.	Residence in skilled nursing facility. Yes		
	□ No		
10.	Current use of specific psychoactive medications (e.g.,certain antidepressants, neuroleptics, chronic anxiolytics or sedative hypnotics, etc.). Current use of warfarin (exclusionary for lumbar puncture). \[\sum \text{Yes} \] \[\sum \text{No} \]		
11.	Investigational agents are prohibited one month prior to entry and for the duration of the trial. \(\sum \) Yes \(\sum \) No		
12.	Participation in clinical studies involving neuropsychological measures being collected more than one time per year. $\hfill Yes \hfill No$		
13.	Exclusion for amyloid imaging with 18F–AV-45: Current or recent participation in any procedures involving radioactive agents such that the total radiation dose exposure to the subject in any given year would exceed the limits of annual and total dose commitment set forth in the US Code of Federal Regulations (CFR) Title 21 Section 361.1. Yes No		
14.	Exceptions to these guidelines may be considered on a case-by-case basis at the discretion of the protocol director (Dr. Petersen). Yes No		



Geriatric Depression Scale					
Visit: EMCI Screening					
ADNI PARTICIPANT NUMBER EXAMINER INITIALS EXAMINATION DATE					
INSTRUCTIONS: Say to the participant: "In the next part of this interview, I will ask you questions about your feelings. Some of the questions I will ask you may not apply, and some may make you feel uncomfortable. For each question, please answer "yes" or "no," depending on how you have been feeling in the past week, including today."					
Information Source: Participant Visit Telephone Call					
\square Check here if Participant is unable to complete the GDS based on the clinician's best judgement.					
If unable, explain:					
 1. Are you basically satisfied with your life? ☐ Yes (0) ☐ No (1) 					
2. Have you dropped many of your activities and interests?☐ Yes (1)☐ No (0)					
3. Do you feel that your life is empty? ☐ Yes (1) ☐ No (0)					
4. Do you often get bored? ☐ Yes (1) ☐ No (0)					
5. Are you in good spirits most of the time? ☐ Yes (0) ☐ No (1)					
6. Are you afraid that something bad is going to happen to you?☐ Yes (1)☐ No (0)					
7. Do you feel happy most of the time? ☐ Yes (0) ☐ No (1)					

Alzheimer's Disease Cooperative S	tudy

Geriatric Depression Scale
Visit: EMCI Screening ADNI PARTICIPANT NUMBER
8. Do you often feel helpless? Yes (1) No (0)
9. Do you prefer to stay at home, rather than going out and doing new things?☐ Yes (1)☐ No (0)
10. Do you feel you have more problems with memory than most?☐ Yes (1)☐ No (0)
11. Do you think its wonderful to be alive now?☐ Yes (0)☐ No (1)
12. Do you feel pretty worthless the way you are now? ☐ Yes (1) ☐ No (0)
13. Do you feel full of energy? ☐ Yes (0) ☐ No (1)
14. Do you feel that your situation is hopeless?☐ Yes (1)☐ No (0)
15. Do you think that most people are better off than you are?☐ Yes (1)☐ No (0)
Total Score:

					VCISIOII				
Alzheimer's Disease Cooperativ	Clinical De	Scoring See procedures mar instructions Sum of Boxe							
ADNI PARTICIPAN									
INSTRUCTIONS: Score only as decline from previous usual level due to cognitive loss, not impairment due to other factors. INFORMATION SOURCE: Participant Visit Telephone Call									
SCORE	HEALTHY CDR 0	QUESTIONABLE DEMENTIA CDR 0.5	MILD DEMENTIA CDR 1	MODERATE DEMENTIA CDR 2	SEVERE DEMENTIA CDR 3				
MEMORY	No memory loss or slight inconsistent forgetfulness	Consistent slight forgetfulness; partial recollection of events; "benign" forgetfulness	Moderate memory loss; more marked for recent events; defect interferes with everyday activities	Severe memory loss; only highly learned material re- tained; new material rapidly lost	Severe memory loss, only fragments remain				
ORIENTATION	Fully oriented	Fully oriented except for slight difficulty with time relationships	Moderate difficulty with time relationships; oriented for place at examination; may have geographic disorientation elsewhere	Severe difficulty with time relationships; usually disoriented in time, often to place	Oriented to person only				
JUDGMENT AND PROBLEM SOLVING	Solves everyday problems and business & financial af- fairs well; judgment good in relation to past performance	Slight impairment in solving problems, similarities, differences	Moderate difficulty in handling problems, similarities, differences; social judgment usually maintained	Severely impaired in han- dling problems, similarities, differences; social judgment usually impaired	Unable to make judgments or solve problems				
COMMUNITY AFFAIRS	Independent function at usual level in job, shopping, volunteer and social groups	Slight impairment in these activites	Unable to function inde- pendently at these activities though may still be engaged in some; appears normal to casual inspection	No pretense of function out Appears well enough to be taken to functions outside a family home					
HOME AND HOBBIES	Life at home, hobbies, intellectual interests well maintained	Life at home, hobbies, intellectual interests slightly impaired	Mild but definite impairment of function at home; more difficult chores abandoned; more complicated hobbies and interests abandoned	Only simple chores preserved; very restricted interests, poorly maintained	No significant function in home				
PERSONAL CARE	Fully capabl	le of self care	Needs prompting	Requires assistance in dressing, hygiene, keeping of personal effects	Requires much help with personal care; frequent incontinence				



ADOS									
	Clinical Dementia Rating								
	Visit: EMCI Screening								
г	ADNI PARTICIPANT NUMBER EXAMINER INITIALS	EX	AMIN	NATION DATE		_			
Ĺ		MONTH	DAY	YEAF					
	s is a semi-structured interview. Please ask all of these questions. A	sk any addition	onal	questions	`				
	ressary to determine the subject's CDR. Please record information f	rom the addi	tiona	al questions.					
Me	mory Questions for Study Partner:		_						
1.	Does he/she have a problem with his/her memory or thinking?	∐ Yes		No					
_	If yes, is this a consistent problem (as opposed to inconsistent)?	☐ Yes		No					
2.	Can he/she recall recent events?	☐ Usually		Sometimes		•			
3.	Can he/she remember a short list of items (shopping)?	′		Sometimes	Ш	Rarely			
4. -	Has there been some decline in memory during the past year?	☐ Yes ☐ Yes		No					
5.	Is his/her memory impaired to such a degree that it would have interfered with his/her activities of daily life a few years ago (or pre-retirement activities)? (Collateral sources opinion)	∟ Yes		No					
6.	Does he/she completely forget a major event (e.g., trip, party, family wedding) within a few weeks of the event?	☐ Usually		Sometimes		Rarely			
7.	Does he/she forget pertinent details of the major event?	☐ Usually		Sometimes		Rarely			
8.	Does he/she completely forget important information of the	☐ Usually		Sometimes		Rarely			
	distant past (e.g., birth date, wedding date, place of employment))?							
9.	Tell me about some recent event in his/her life that he/she should details such as location of the event, time of day, participants, how how the subject or other participants got there.)			_					
	Within 1 week:								
	Within 1 month:								
10.	When was he/she born?								
11.	Where was he/she born?								
12.	What was the last school he/she attended?								
	Name:								
	Place:								
	Grade:								
13.	What was his/her main occupation/job (or spouse's job if subject	was not emp	loyed	d)?					
14.	What was his/her last major job (or spouse's job if subject was not	t employed)?							
15.	When did he/she (or spouse) retire and why?								

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				Vis	it: EMC	S Scree	ning			
				ADNI	PARTICI	PANT NU	JMBER	7		
					<u></u> s					
Or	ientation (Questions	for Study	/ Partner:						
Но	w often do	es he/she l	know of t	he exact:						
1.	Date of th	ne month?								
] Usually		Sometimes		Rarely		Don't Know		
2.	Month?									
		Usually		Sometimes		Rarely		Don't Know		
3.	Year?									
		Usually		Sometimes		Rarely		Don't Know		
4.	Day of the	,						5 64		
	L	J Usually	Ш	Sometimes	ш	Rarely	Ш	Don't Know		
5.	Does he/s	she have di	ifficulty w	ith time relat	ionshins	: (when	events h	annened in rela	tion to each other)?	
]		Usually		Sometimes		Rarely		Don't Know	tion to each other).	
		·				ŕ				
6.	Can he/sh	ne find his/	her way a	bout familiar	streets?					
		Usually		Sometimes		Rarely		Don't Know		
7.	How ofte	_	she know	_	rom one	-			r neighborhood?	
		J Usually		Sometimes	Ш	Rarely	Ш	Don't Know		
8.	How ofte	n can he/sł	ne find his	s/her way abo	out indo	ors?				
		Usually		Sometimes		Rarely		Don't Know		



Clinical Domontia Pating
Clinical Dementia Rating
Visit: EMCI Screening
ADNI PARTICIPANT NUMBER
Judgment and Problem Solving Questions for Study Partner:
 In general, if you had to rate his/her abilities to solve problems at the present time, would you consider them:
☐ As good as they have ever been
Good, but not as good as before
☐ Fair
☐ Poor
☐ No ability at all
2. Rate his/her ability to cope with small sums of money (e.g., make change, leave a small tip): \[\sum_ \] No Loss
☐ Some Loss
☐ Severe Loss
3. Rate his/her ability to handle complicated financial or business transactions (e.g., balance checkbook, pay bills):
□ No Loss
☐ Some Loss
☐ Severe Loss
4. Can he/she handle a household emergency (e.g., plumbing leak, small fire)?
☐ As well as before
☐ Worse than before because of trouble thinking
☐ Worse than before, another reason (why)
5. Can he/she understand situations or explanations?
☐ Usually ☐ Sometimes ☐ Rarely ☐ Don't Know
6. Does he/she behave* appropriately (i.e., in his/her usual [pre-morbid] manner) in social situations and interactions with other people?
☐ Rarely ☐ Sometimes ☐ Usually ☐ Don't Know
*This item rates behavior, not appearance

	Version
Alzhe	imer's Disease Cooperative Study
	Clinical Dementia Rating
	Page 4 of 10
	Visit: EMCI Screening
	ADNI PARTICIPANT NUMBER
Co	mmunity Affairs Questions for Study Partner:
Oc	cupational
1.	Is the subject still working? \square Yes \square No \square N/A
	If not applicable, proceed to item 4
	If yes, proceed to item 3 If no, proceed to item 2
2.	Did memory or thinking problems contribute to the subject's decision
۷.	to retire? (Question 4 is next)
3.	Does the subject have significant difficulty in his/her job because of problems with memory or thinking? Rarely or Never Sometimes Usually Don't Know
So	cial
4.	Did he/she ever drive a car?
	Does the subject drive a car now?
	If no, is this because of memory or thinking problems? \square Yes \square No
5.	If he/she is still driving, are there problems or risks because of poor thinking? \Box Yes \Box No
*6.	Is he/she able to independently shop for needs?
	☐ Rarely or Never ☐ Sometimes ☐ Usually ☐ Don't Know
	(Needs to be accompanied (Shops for limited number on any shopping trip) of items; buys duplicate items
	or forgets needed items)
7.	Is he/she able to independently carry out activities outside the home?
	☐ Rarely or Never ☐ Sometimes ☐ Usually ☐ Don't Know
	(Generally unable to perform (Limited and/or routine, (Meaningful participation
	activities without help) e.g., superficial in activities, e.g., voting.) participation in church
	or meetings; trips to
	beauty parlor)
8.	Is he/she taken to social functions outside a family home?
	If no, why not?
9.	Would a casual observer of the subject's behavior think the subject was ill?
10.	If in nursing home, does he/she participate well in social functions (thinking)? L Yes L No
IM	PORTANT:
	there enough information to rate the subject's level of impairment in community affairs?
lf r	not, please probe further.
Со	mmunity Affairs: Such as going to church, visiting friends and family, political activities, professional
	ganizations such as bar association, other professional groups, social clubs, service organizations, educational
pro	ograms.
*Ple	ease add notes if needed to clarify subject's level of functioning in this area.



	Clinical Dementia Rating						
	Page 5 of 10 Visit: EMCI Screening						
	ADNI PARTICIPANT NUMBER						
Но	me and Hobbies Questions for Study Partner:						
1a.	What changes have occurred in his/her abilities to perform household chores?						
1b.	What can he/she still do well?						
2a.	What changes have occurred in his/her ability to perform hobbies?						
2b.	What can he/she still do well?						
3.	If in nursing home, what can he/she no longer do well (H and H)?						
	Everyday Activities (Blessed):						
Eve	eryday Activities (Blessed):						
Eve	Pryday Activities (Blessed): No Loss Severe Loss						
Eve 4.							
	Ability to perform household tasks No Loss Severe Loss 0 0.5 1						
	Ability to perform household tasks No Loss Severe Loss 0 0.5 1						
4.	Ability to perform household tasks 0 0.5 1 Please describe: Is he/she able to perform household chores at the level of:						
4.	Ability to perform household tasks 0 0.5 1 Please describe: Is he/she able to perform household chores at the level of: (Pick one. Study Partner does not need to be asked directly) No meaningful function.						
4.	Ability to perform household tasks 0 0.5 1 Please describe: Is he/she able to perform household chores at the level of: (Pick one. Study Partner does not need to be asked directly) No meaningful function. (Performs simple activities, such as making a bed, only with much supervision) Functions in limited activities only.						
4.	Ability to perform household tasks 0 0.5 1 Please describe: Is he/she able to perform household chores at the level of: (Pick one. Study Partner does not need to be asked directly) No meaningful function. (Performs simple activities, such as making a bed, only with much supervision) Functions in limited activities only. (With some supervision, washes dishes with acceptable cleanliness; sets table) Functions independently in some activities.						

IMPORTANT:

Is there enough information to rate the subject's level of impairment in HOME & HOBBIES? If not, please probe further.

Homemaking Tasks: Such as cooking, laundry, cleaning, grocery shopping, taking out garbage, yard work, simple care, maintenance, and basic home repair.

Hobbies: Sewing, painting, handicrafts, reading, entertaining, photography, gardening, going to theater or symphony, woodworking, participation in sports.

Clinical Dementia Rating

VISIT:	FINICI	Scr	eenir	ıg
ADNI PA	ARTICIF	PANT	NUM	BER

		0	-		
		0			
		_			

Personal Care Questions for Study Partner:

*What is your estimate of his/her mental ability in the following areas:

	Unaided	Occasionally misplaced buttons, etc.	Wrong sequence commonly forgotten items	Unable to dress
A. Dressing (Blessed)	0	1	2	3
	Unaided	Needs prompting	Sometimes needs help	Always or nearly always needs help
B. Washing, grooming	0	1	2	3
	Cleanly; proper utensils	Messily; spoon	Simple solids	Has to be fed completely
C. Eating habits	0	1	2	3
	Normal complete control	Occasionally wets bed	Frequently wets bed	Doubly incontinent
D. Sphincter control (Blessed)	0	1	2	3

^{*}A box score of 1 can be considered if the subject's personal care is impaired from a previous level, even if they do not receive prompting.

			1.	/isit: EMCI	of 10 Screening		
					ANT NUMBER		
				s_			
mor	y Questions f	for Subj	ject:				
Do	you have prob	blems w	ith memory or t	thinking?	☐ Yes	□ No	
thin	ng about those	e? (Pron	npt for details, if	needed, su	w recent experienc ch as location of th e subject or other p	e event, time	e of day, participa
			Within 1 week				
1.0	- Largely corre	ect					
0.5							
0.0	- Largely inco	rrect					
			Within 1 month	1			
1.0							
1.0	- Largely corre	ect					
	- Largely corre	ect					
0.5	- '						
0.5 0.0 I wi	- Largely inco	rrect iame an			a few minutes. Rep maximum of three		e and address afto
0.5 0.0 I wi (Re	- Largely inco ill give you a n peat until the ments	rrect name an phrase 1	is correctly repe 2	ated or to a	maximum of three	e trials.) 5	e and address afto
0.5 0.0 I wi (Re	- Largely inco ill give you a n peat until the ments	rrect name an phrase 1 John	is correctly repe 2 Brown,	ated or to a 3 42	maximum of three 4 Market Street,	trials.) 5 Chicago	e and address afto
0.5 0.0 I wi (Re	- Largely inco ill give you a n peat until the ments	rrect name an phrase 1	is correctly repe 2	ated or to a	maximum of three	e trials.) 5	e and address afto
0.5 0.0 I wi (Re <u>Eler</u>	- Largely inco ill give you a n peat until the ments	rrect name an phrase 1 John John John	is correctly repe 2 Brown, Brown,	3 42 42 42 42	Market Street, Market Street, Market Street,	trials.) 5 Chicago Chicago	e and address afto
0.5 0.0 I wi (Re Eler	- Largely inco ill give you a n peat until the ments	rrect name an phrase 1 John John John	is correctly repe 2 Brown, Brown, Brown, eated correctly i	3 42 42 42 42 n each trial	Market Street, Market Street, Market Street,	trials.) 5 Chicago Chicago Chicago	
0.5 0.0 I wi (Re Eler (Un	- Largely inco ill give you a n peat until the ments anderline eleme	rrect name an phrase 1 John John John ents repo	is correctly repe 2 Brown, Brown, Brown, eated correctly i	3 42 42 42 42 n each trial	Market Street, Market Street, Market Street,	trials.) 5 Chicago Chicago Chicago	
0.5 0.0 I wii (Re Eler (Un Wh	- Largely inco ill give you a n peat until the ments anderline eleme nen were you b	rrect name an phrase 1 John John John ents repe	is correctly repe 2 Brown, Brown, Brown, eated correctly i	ated or to a 3 42 42 42 42 in each trial	Market Street, Market Street, Market Street,	trials.) 5 Chicago Chicago Chicago	
0.5 0.0 I wi (Re Eler (Un Wh Wh	- Largely inco ill give you a n epeat until the ments nderline eleme en were you b here were you last	rrect name an phrase 1 John John John ents repo corn? born? t school	is correctly repe 2 Brown, Brown, Brown, eated correctly i	ated or to a 3 42 42 42 7 an each trial	Market Street, Market Street, Market Street,	trials.) 5 Chicago Chicago Chicago	
0.5 0.0 I wi (Re Eler (Un Wh Wh Nar	- Largely incomill give you an epeat until the ments anderline elemente were you be the was the last me	rrect name an phrase 1 John John John ents repe corn? born? t school	is correctly repe 2 Brown, Brown, Brown, eated correctly i	ated or to a 3 42 42 42 n each trial	Market Street, Market Street, Market Street,	trials.) 5 Chicago Chicago Chicago	
0.5 0.0 I wi (Re Eler (Un Wh Wh Nar Place	- Largely incomill give you an epeat until the ments enderline elementer were you be the was the last me	rrect name an phrase 1 John John ents repe corn? born? t school	is correctly repe 2 Brown, Brown, Brown, eated correctly i	ated or to a 3 42 42 42 in each trial	Market Street, Market Street, Market Street,	trials.) 5 Chicago Chicago Chicago	
0.5 0.0 I wi (Re Eler (Un Wh Wh Nar Plac	- Largely incomill give you an epeat until the ments Inderline elemente were you be the were you be the last mas the last me	rrect name an phrase 1 John John John ents repo corn? born? t school	is correctly repe 2 Brown, Brown, Brown, eated correctly i you attended?	ated or to a 3 42 42 42 for each trial	Market Street, Market Street, Market Street,	trials.) 5 Chicago Chicago Chicago	
0.5 0.0 I wi (Re Eler (Un Wh Wh Nar Plac Wh	- Largely incomill give you an epeat until the ments Inderline elemente were you be the were you be the last was the last me	rrect name an phrase 1 John John John ents repo born? t school	is correctly repe 2 Brown, Brown, Brown, eated correctly i you attended? upation/job (or	ated or to a 3 42 42 42 n each trial arade spouse if not employed	Market Street, Market Street, Market Street, Market Street, ot employed)?	trials.) 5 Chicago Chicago Chicago	
0.5 0.0 I wi (Re Eler (Un Wh Wh Nar Place Wh Wh	- Largely incomill give you an epeat until the ments Inderline elemente were you be the were were you be the last was the last me	rrect name an phrase 1 John John John ents repe born? t school nain occurst majours	is correctly repe 2 Brown, Brown, Brown, eated correctly i you attended? upation/job (or	ated or to a 3 42 42 42 are ach trial spouse if not employ?	Market Street, Market Street, Market Street, Market Street, ot employed)?	trials.) 5 Chicago Chicago Chicago	
0.5 0.0 I wi (Re Eler (Un Wh Wh Nar Plac Wh Wh Rep	- Largely incomill give you an epeat until the ments Inderline elemente were you be the were were you be the last was the last me	rrect name an phrase 1 John John John ents repe born? t school nain occurst majours	is correctly reperverse 2 Brown, Brown, Brown, eated correctly in the second se	ated or to a 3 42 42 42 are ach trial spouse if not employ?	Market Street, Market Street, Market Street, Market Street, ot employed)?	trials.) 5 Chicago Chicago Chicago	

/	Clinical Dementia Rating									
Visit: EMCI Screening										
	ADNI PARTICIPANT NUMBER									
Or	ientation Questions for Subject:									
Re	cord the subject's answer verbatim for each question:									
1.	What is the date today?	☐ Correct	☐ Incorrect							
2.	What day of the week is it?	☐ Correct	☐ Incorrect							
3.	What is the month?	☐ Correct	☐ Incorrect							
4.	What is the year?	☐ Correct	☐ Incorrect							
5.	What is the name of this place?	☐ Correct	☐ Incorrectt							
6.	What town or city are we in?	☐ Correct	☐ Incorrect							
7.	What time is it?	☐ Correct	☐ Incorrect							
8.	Does the subject know who the study partner is (in your judgment)?	☐ Correct	☐ Incorrect							

Alzheimer's Disease Cooperative S	tud

ADE	5			
	Clinical Dementi	a Ratin	g	
	Visit: EMCI Screer			
	ADNI PARTICIPANT NU	MBER		
Instruct	and Problem Solving Questions for Subject: ions: If initial response by subject does not merit a so s best understanding of the problem. Circle nearest	•	ss the matter to	o identify the
Similarities	:			
Exampl	e: "How are a pencil and pen alike?" (writing instrum	ents) <u>Subject's res</u> j	<u>oonse</u>	
1.	turnipcauliflower (0 = vegetables) (1 = edible foods, living things, can be cooked, etc.) (2 = answers not pertinent; differences; buy item))		
2.	deskbookcase (0 = furniture, office furniture, both hold books) (1 = wooden, legs) (2 = not pertinent; differences; buy item)			
•	: e: "What is the difference between sugar and vinega	r?" (sweet vs. Subject's res _l		
3.	liemistake (0 = one deliberate, one unintentional) (1 = one bad the other good - or explains only one) (2 = anything else, similarities))		
4.	rivercanal (0 = natural - artificial) (2 = anything else)			
Calculation	, , ,	<u>onse</u>		
5.	How many nickels in a dollar?		☐ Correct	☐ Incorrect
6.	How many quarters in \$6.75?		☐ Correct	☐ Incorrect
7.	Subtract 3 from 20 and keep subtracting 3 from each new number all the way down.		☐ Correct	☐ Incorrect
Judgment:				
8.	Upon arriving in a strange city, how would you local 0 = try the telephone book, city directory, go to the 1 = call the police, call operator (usually will not give 2 = no clear response	e courthouse	•	
9.	Subject's assessment of disability and station in life the examination (may have covered, but rate here) Good Insight Partial Insight			he/she is present at

Version 6 Alzheimer's Disease Cooperative Study Clinical Dementia Rating Visit: EMCI Screening ADNI PARTICIPANT NUMBER S **Notes, Comments, Summary Statement**

Neuropsychiatric Inventory Q
Page 1 of 3
Visit: EMCI Subjects Baseline ADNI PARTICIPANT NUMBER EXAMINER INITIALS EXAMINATION DATE
MONTH DAY YEAR
Instructions: For each question, use the participant's name where {P} appears. Ask the participant's Study Partner to indicate whether any of the {P}'s behaviors listed below occurred during the previous four weeks. If so, use the following rating scales to rate the severity of the behavior. Information Source Participant Visit Telephone Call
A. DELUSIONS Does {P} believe that others are stealing from him/her, or planning to harm him/her in some way? No Yes N/A Severity Ratings 1 - Mild (noticeable, but not a significant change). 2 - Moderate (significant, but not a dramatic change). 3 - Severe (very marked or prominent. A dramatic change).
 B. HALLUCINATIONS Does {P} act as if he/she hears voices? Does he/she talk to people who are not there? No Yes N/A Severity Ratings 1 - Mild (noticeable, but not a significant change). 2 - Moderate (significant, but not a dramatic change). 3 - Severe (very marked or prominent. A dramatic change).
C. AGITATION/AGGRESSION Is {P} stubborn and resistive to help from others? No Yes N/A Severity Ratings 1 - Mild (noticeable, but not a significant change). 2 - Moderate (significant, but not a dramatic change). 3 - Severe (very marked or prominent. A dramatic change).
 D. DEPRESSION/DYSPHORIA Does {P} act as if he/she is sad or in low spirits? Does he/she cry? No Yes N/A Severity Ratings 1 - Mild (noticeable, but not a significant change). 2 - Moderate (significant, but not a dramatic change). 3 - Severe (very marked or prominent. A dramatic change).



/	Neuropsychiatric Inventory Q
	Visit: EMCI Subjects Baseline
	ADNI PARTICIPANT NUMBER
E.	ANXIETY Does {P} become upset when separated from you? Does he/she have any other signs of nervousness, such as shortness of breath, sighing, being unable to relax, or feeling excessively tense? No Yes N/A Severity Ratings 1 - Mild (noticeable, but not a significant change). 2 - Moderate (significant, but not a dramatic change). 3 - Severe (very marked or prominent. A dramatic change).
F.	ELATION/EUPHORIA Does {P} appear to feel too good or act excessively happy? ☐ No ☐ Yes ☐ N/A Severity Ratings ☐ 1 - Mild (noticeable, but not a significant change). ☐ 2 - Moderate (significant, but not a dramatic change). ☐ 3 - Severe (very marked or prominent. A dramatic change).
G.	APATHY/INDIFFERENCE Does {P} seem less interested in his/her usual activities and in the activities and plans of others? No Yes N/A Severity Ratings 1 - Mild (noticeable, but not a significant change). 2 - Moderate (significant, but not a dramatic change). 3 - Severe (very marked or prominent. A dramatic change).
H.	DISINHIBITION Does {P} seem to act impulsively? For example, does {P} talk to strangers as if he/she knows them, or does {P} say things that may hurt people's feelings? No Yes N/A Severity Ratings 1 - Mild (noticeable, but not a significant change). 2 - Moderate (significant, but not a dramatic change). 3 - Severe (very marked or prominent. A dramatic change).



	Neuropsychiatric Inventory Q Page 3 of 3
	Visit: EMCI Subjects Baseline
	ADNI PARTICIPANT NUMBER
	s – s – s – s – s – s – s – s – s – s –
waiti [[TABILITY/LABILITY Is {P} impatient or cranky? Does he/she have difficulty coping with delays or ing for planned activities? No Yes N/A Severity Ratings 1 - Mild (noticeable, but not a significant change). 2 - Moderate (significant, but not a dramatic change). 3 - Severe (very marked or prominent. A dramatic change).
hand [[[RRANT MOTOR BEHAVIOR Does {P} engage in repetitive activities, such as pacing around the house, dling buttons, wrapping strings, or doing other things repeatedly? No Yes N/A Severity Ratings 1 - Mild (noticeable, but not a significant change). 2 - Moderate (significant, but not a dramatic change). 3 - Severe (very marked or prominent. A dramatic change).
	Does {P} awaken you during the night, rise too early in the morning, or take excessive naps during the day? No Yes N/A Severity Ratings 1 - Mild (noticeable, but not a significant change). 2 - Moderate (significant, but not a dramatic change). 3 - Severe (very marked or prominent. A dramatic change).
	ETITE AND EATING DISORDERS Has {P} lost or gained weight, or had a change in the food he/she likes? No Yes N/A ieverity Ratings 1 - Mild (noticeable, but not a significant change). 2 - Moderate (significant, but not a dramatic change). 3 - Severe (very marked or prominent. A dramatic change).
Total Sco	ore

Functional Assessment Questionnaire
Page 1 of 2 Visit: EMCI Subjects Baseline
ADNI PARTICIPANT NUMBER EXAMINER INITIALS EXAMINATION DATE
MONTH DAY YEAR
Instructions: Select the most accurate representation of the participant's level of ability to perform each activity over the preceding four weeks, based on the Study Partner's assessment.
Information Source
☐ Participant Visit ☐ Telephone Call
1. Writing checks, paying bills, or balancing checkbook. Normal (0) Never did, but could do now (0) Never did, would have difficulty now (1) Has difficulty, but does by self (1) Requires assistance (2) Dependent (3)
2. Assembling tax records, business affairs, or other papers. Normal (0) Never did, but could do now (0) Never did, would have difficulty now (1) Has difficulty, but does by self (1) Requires assistance (2) Dependent (3)
3. Shopping alone for clothes, household necessities, or groceries. Normal (0) Never did, but could do now (0) Never did, would have difficulty now (1) Has difficulty, but does by self (1) Requires assistance (2) Dependent (3)
 4. Playing a game of skill such as bridge or chess, working on a hobby. Normal (0) Never did, but could do now (0) Never did, would have difficulty now (1) Has difficulty, but does by self (1) Requires assistance (2) Dependent (3)
5. Heating water, making a cup of coffee, turning off the stove. Normal (0) Never did, but could do now (0) Never did, would have difficulty now (1) Has difficulty, but does by self (1) Requires assistance (2) Dependent (3)

A	Functional Assessment Questionnaire
	Visit: EMCI Subjects Baseline
	ADNI PARTICIPANT NUMBER
6.	Preparing a balanced meal.
	☐ Normal (0) ☐ Never did, but could do now (0)
	☐ Never did, but could do now (0) ☐ Never did, would have difficulty now (1)
	Has difficulty, but does by self (1)
	Requires assistance (2)
	Dependent (3)
7.	Keeping track of current events.
	□ Normal (0)
	Never did, but could do now (0)
	☐ Never did, would have difficulty now (1) ☐ Has difficulty, but does by self (1)
	Requires assistance (2)
	Dependent (3)
8.	Paying attention to and understanding a TV program, book, or magazine.
	Normal (0)
	☐ Never did, but could do now (0)
	☐ Never did, would have difficulty now (1)
	☐ Has difficulty, but does by self (1) ☐ Requires assistance (2)
	Dependent (3)
9.	Remembering appointments, family occasions, holidays, medications.
	□ Normal (0)
	Never did, but could do now (0)
	☐ Never did, would have difficulty now (1)
	☐ Has difficulty, but does by self (1) ☐ Requires assistance (2)
	Dependent (3)
10.	Traveling out of the neighborhood, driving, or arranging to take public transportation.
	□ Normal (0)
	Never did, but could do now (0)
	☐ Never did, would have difficulty now (1)
	☐ Has difficulty, but does by self (1) ☐ Requires assistance (2)
	Dependent (3)
_	
Tot	cal Score

Alzheimer's Disease Cooperative Study
Vital Signs
Visit: EMCI Screening ADNI PARTICIPANT NUMBER EXAMINER INITIALS EXAMINATION DATE
MONTH DAY YEAR
1. Measure weight with shoes off. Round up or down to the nearest tenth.
1b. Units ☐ Pounds
☐ Kilograms
2. Measure height with shoes off. Round up or down to the nearest tenth. (Screening Visit Only)
2b. Units ☐ Inches
☐ Centimeter
3. Seated Blood Pressure
mmHg
systolic diastolic 4. Seated Pulse Rate (beats per minute)
bpm
5. Respirations (per minute)
6. Temperature
6b. Temperature Source Oral
Tympanic
☐ Other 6c. Units
☐ Farenheit
Celsius
7. Comments regarding vital signs:

				version
Alzheimer's Disease Cooperative Study				
ADES			Physical Exam	
			Visit: EMCI Screening	
ADNI PARTICIPAI	NT NUMBER		EXAMINER INITIALS	EXAMINATION DATE
				MONTH DAY YEAR
	NORMAL ABN	IORMAL	If "abnormal," must provide details:	
1. General Appearance				
2. Head, Eyes, Ears, Nose, Throat				
3. Neck				
4. Chest				
5. Heart				
6. Abdomen				
7. Extremities				
8. Edema				
9. Peripheral Vascular				
10. Skin and Appendages		_		
(e.g., ecchymosis)		_ _		
11. Musculoskeletal				
12. Back				·····
13. Other			Specify:	
14. General comments				
15. Confirm clinician's qualifying crede	entials:			
□ M.D. □ P.A.	□ D.O.	□N.P.	Other (specify)	
16. Based on the Physical Examination	n, clinician must ch	eck appropri	ate box below:	
Findings consistent with e	ligibility for study			
Participant is not eligible f	or study			
17. Clinician's signature (required)_			Da	te

					VCISIOII
Alzheimer's Disease Cooperative Study					
ADES		N.	lauralagical Evan		
		l,	Neurological Exan	11	
A DAU DA DTIQIDAA	TAILIMDED		Visit: EMCI Screening EXAMINER INITIALS	EXAMINATION DATE	
ADNI PARTICIPAN	I NOMBER	\neg	EXAMINER INITIALS	EXAMINATION DATE	\neg
				MONTH DAY YEAR	
	Absent	Present	If "present", must provide detai		
1. Significant Visual Impairment					
2. Significant Auditory Impairment					
3. Tremor					
	Normal	Abnormal			
4. Level of Consciousness					
5. Cranial Nerves					
6. Motor Strength					
7. Cerebellar:					
a. Finger to Nose					
b. Heel to Shin					
8. Sensory					
9. Deep Tendon Reflexes					
10. Plantar Reflexes					
11. Gait					
12. Other					
13. General comments					
13. General Comments					
14. Confirm clinician's qualifying crede	ntials:				
□ M.D. □ P.A.	□ D.O.	□ N.P.	Other (specify)		
15. Based on the Neurological Examina	tion, clinician	must check ap	opropriate box below:		
Findings consistent with el		_	rticipant is not eligible for study		
	J,		and the second s		
16 Clinician's Signature (required)			Date		

	Version 6
Alzheimer's Disease Cooperative Study ADOS Participant Demographics	
Page 1 of 2	
Visit: EMCI Screening ADNI PARTICIPANT NUMBER EXAMINER INITIALS EXAMINATION DATE	
S MONTH DAY YEAR	
Information Source: Participant Visit Telephone Visit	
1. Participant Gender: ☐ Male ☐ Female	
2a. Participant Month of Birth	
MONTH	
2b. Partipant Year of Birth YEAR	
3. Participant Handedness: ☐ Right ☐ Left	
4. Participant Marital Status: Married Widowed Divorced Never Married Unknown	
5. Participant Education (0 - 20 years):	
5a. Does the participant have a work history sufficient to exclude mental retardation? ☐ Yes ☐ No	
6a. Primary occupation during most of adult life:	
6b. Most recent occupation:	
7. Participant Retired?	

☐ Yes ☐ No Retirement Date:

Participant Demographics
Page 2 of 2 Visit: EMCI Screening
ADNI PARTICIPANT NUMBER
8. Type of Participant residence (If Other, please specify): House Condo/Co-op (owned) Apartment (rented) Mobile Home Retirement Community Assisted Living Skilled Nursing Facility Other (Specify):
9. Language to be used for testing the Participant: ☐ English ☐ Spanish
 10. Participant's Primary Language (If Other, please specify): English Spanish Other (specify): 11a. Year of onset of Mild Cognitive symptoms (best estimate):
Trail real of original cognitive symptoms (sest estimate).
11b. Year of onset of Alzheimer's disease symptoms (best estimate):
12. Ethnic Category: Hispanic or Latino Not Hispanic or Latino Unknown
13. Racial Category: American Indian or Alaskan Native Asian Native Hawaiian or Other Pacific Islander Black or African American White More than one race Unknown

	Version
Alzheimer's Disease C	Cooperative Study
ADES	
	Family History Questionnaire
	Page 1 of 2 Visit: EMCI Screening
ADNI PAF	RTICIPANT NUMBER EXAMINER INITIALS EXAMINATION DATE
	S MONTH DAY YEAR
Instructions: NOTE:	Ask the participant and study partner about the presence of dementia and Alzheimer's disease for the following biological (blood) relatives. Dementia should be indicated if a relative has a history of senility or progressive memory problems over time. If the participant has siblings, answer "Yes" to question #3 and provide information about his/her history of dementia. Alzheimer's Disease should only be answered when Dementia is answered "Yes."
Information Sou Particip Telepho	ant Visit
☐ Particip ☐ Study P	who provided the information collected for this questionnaire: ant only artner only articipant and Study Partner
☐ Alzheim ☐	Yes No Don't Know er's Disease
Alzheim	Yes No Don't Know er's Disease Yes

Family History Questionnaire							
Page 2 of 2 Visit: EMCI Screening							
			PANT NUMBER				
		s					
☐ Yes ☐ No	rticipant have any sib		ease provides additional information	below.)			
Sibling 1: Gend	der:	Dementia: \square	Yes Alzheimer's Disease: No Don't Know	Yes No Don't Know			
Sibling 2: Gen	der:	Dementia: 🔲	Yes Alzheimer's Disease: No Don't Know	☐ Yes ☐ No ☐ Don't Know			
Sibling 3: Gen	der:	Dementia: 🔲	Yes Alzheimer's Disease: No Don't Know	☐ Yes ☐ No ☐ Don't Know			
Sibling 4: Gen	der:	Dementia: 🔲	Yes Alzheimer's Disease: No Don't Know	☐ Yes ☐ No ☐ Don't Know			
Sibling 5: Gen	der:	Dementia: 🔲	Yes Alzheimer's Disease: No Don't Know	☐ Yes ☐ No ☐ Don't Know			
Sibling 6: Gen	der:	Dementia:	Yes Alzheimer's Disease: No Don't Know	☐ Yes ☐ No ☐ Don't Know			
Sibling 7: Gend	der:	Dementia: \square	Yes Alzheimer's Disease: No Don't Know	☐ Yes ☐ No ☐ Don't Know			
Sibling 8: Gen	der:	Dementia: 🔲	Yes Alzheimer's Disease: No Don't Know	☐ Yes ☐ No ☐ Don't Know			
Sibling 9: Gen	der:	Dementia:	Yes Alzheimer's Disease: No Don't Know	Yes No Don't Know			

Alzhe	imer's Disease Cooperative Study					
A	AD©S Medical History					
				Visit: EMCI Screening		
	ADNI PARTICIPAN	T NU	MBER	EXAMINER INITIALS EXAMINATION DATE		
	s			MONTH DAY YEAR		
INSTRUCTIONS: Please review all significant relevant medical history with the participant and indicate whether the participant has or has had a condition/problem within each system by checking the yes or no box. If YES is checked please proceed to the Medical History Supplemental form and provide complete details.						
In	Information Source: Participant Visit Telephone Call					
	REVIEW OF SYSTEMS	YES	NO	YES NO		
1.	Psychiatric			14. Alcohol Abuse		
2.	Neurologic			If Yes to Alcohol Abuse:		
3.	Head, Eyes, Ears, Nose, Throat			14a. During period of alcohol abuse, estimate the average number of drinks per day:		
4.	Cardiovascular			14b. Duration of abuse (years):		
	Respiratory	П	П	14c. Period of time since end of abuse (years):		
		\Box	\Box	15. Drug Abuse		
	Hepatic			16. Smoking		
	Dermatologic-Connective Tissue			If Yes to Smoking:		
8.	16a. During periods of smoking, the average number of packs/day:			16a. During periods of smoking, the average number of packs/day:		
9.	Endocrine-Metabolic			16b. Duration (years):		
10.	Gastrointestinal			16c. If no longer smoking, provide period of time since stopped smoking (years):		
11.	Hematopoietic-Lymphatic			17. Malignancy		
12.	Renal-Genitourinary			18. Major Surgical Procedures		
	Allergies or Drug Sensitivities	П	П	19. Other		
	e. g.co or brug benefitivities	_	_	20. General Comments:		

					version
Alzheimer's Disease Cooperative	•	ınnlaman	tal Earm		
ADES	Medical History - Su		lai FOIII		
	page Visit: EMCI				
ADNI		R INITIALS		EXAMINATION	DATE
	<u> </u>		MONTI	H DAY	YEAR
	form if the participant has indicated a condition or probland provide details for each, including the best estimate				
the parti	cipant is currently taking medication for a condition, the				
recorded	d on the Concurrent Medication Log.				
SYSTEM # / SYSTEM [e.g. 1 / Psychiatric]	DETAILS	ONSET DATE	CURRENT?	IF CURRENT, STABLE?	TYPE OF TREATMENT? (If other, please specify)
			☐ Yes ☐ No	☐ Yes ☐ No	☐ Medication ☐ Other
			☐ Yes ☐ No	☐ Yes ☐ No	☐ Medication ☐ Other
			☐ Yes ☐ No	☐ Yes ☐ No	☐ Medication ☐ Other
			☐ Yes ☐ No	☐ Yes ☐ No	☐ Medication ☐ Other
			☐ Yes ☐ No	☐ Yes ☐ No	☐ Medication ☐ Other
			☐ Yes ☐ No	☐ Yes ☐ No	☐ Medication ☐ Other
			☐ Yes ☐ No	☐ Yes ☐ No	☐ Medication ☐ Other
			☐ Yes ☐ No	☐ Yes ☐ No	☐ Medication ☐ Other
			☐ Yes	☐ Yes	Medication

Version 08/17/10

Alzheimer's Disease Cooperative Study	/
AD©S	

ADOS	odified	Hachii	nski			
	Visit: EMC	CI Screening	l			
ADNI PARTICIPANT NUMBER EXAMINER INITIALS EXAMINATION DATE						
			MONTH DAY YEAR			
Instructions: Select "Absent" or "Present" for each of the clinical features of cognitive impairment listed below. Point values for "Present" are given in parentheses.						
	Present	Absent				
1. Abrupt Onset of Dementia	□ (2)					
2. Stepwise Deterioration of Dementia	□ (1)					
3. Somatic Complaints	□ (1)					
4. Emotional Incontinence	□ (1)					
5. History of Hypertension	□ (1)					
6. History of Stroke	□ (2)					
7. Focal Neurological Symptoms	□ (2)					
8. Focal Neurological Signs	□ (2)					
Total Score (Range 0-12) Sum the values assigned to the boxes checked "Present".						

ADOS					
Key Background Medications Form					
Visit: EMCI Screening					
ADNI PARTICIPANT NUMBER EXAMINER INITIALS EXAMINATION DATE S -					
At this visit, please indicate if participant is on any of the following medications. If none, please check 'None of the above.' Medication must also be entered in Concurrent Medication Log.					
☐ Aricept					
☐ Cognex					
☐ Exelon					
☐ Namenda					
☐ Razadyne					
☐ Anti-depressant medication					
☐ Other behavioral medication					
☐ None of the above					

Alzheimer's Disease Cooperative Study Concurrent Medications			Check box corresponding to visit of last review/update for EMCI Participants:			
	page of sc BL M6 M12 M18					
ADNI PARTICI	PANT NUMBER	EXAMINER INITIALS	EXAMINATION DATE			
		MON	NTH DAY YEAR			
List all medications (prescription and over-the-counter, including vitamins and herbal supplements) taken within three months of Screening. If medication will be continued, leave "Date Ended" blank. At subsequent visits, review each record and update. This form should be stored in the Participant Binder for future updates. Please see Procedures Manual for more detailed CRF/Worksheet instructions. Under "Reason Prescribed" reasons may include the following: Adverse Event (include event number), Therapeutic Use, and Prophylaxis/non-therapeutic use. If the medications continue at the end of the study, check the "Continuing at Final Follow Up" box. No medication 3 months prior to the screening visit						
Medication	Dose/Freq/Route**	Date Began† Month/Day/Year	Date Ended [†] Month/Day/Year	Continuing at Final Reason Prescribed Follow Up?		
	//_			Adverse Event Therapeutic Use Prophylaxis/Non-therapeutic Use		
Reason Prescribed Details*:						
	//_			Adverse Event Therapeutic Use Prophylaxis/Non-therapeutic Use		
Reason Prescribed Details*:						
December 201	//			Adverse Event Therapeutic Use Prophylaxis/Non-therapeutic Use		
Reason Prescrib	_/_/_			Adverse Event Therapeutic Use Prophylaxis/Non-therapeutic Use		
Reason Prescribed Details*: † If exact Month and Day are not known, enter "UNK" for each component. ("UNK" is not acceptable for Year; please ask participant for best estimate)						
** See procedures manual for further	•	in 15 hor acceptable for real, piease ask participant for be	est estimate)			

* For Clinical Monitor use only. Do not enter into the online CRFs.

Diagnosis Summary and Diagnosis Summary - Baseline Changes Forms

Diagnosis at Screening

There are four key inclusion criteria that define the EMCI cohort: presence of a memory complaint, delayed logical memory recall score (education adjusted cut off scores), Mini Mental State Exam score and Clinical Dementia Rating. Based on the values of these key variables and associated cut off scores, the diagnostic status is determined. *The screening diagnosis is captured in the ARM table*.

Diagnosis Assessment and Conversion

The study clinician is responsible for assessing diagnostic status at the initial / baseline visit and is based on his/her clinical judgment. There are no cut off scores associated with delayed logical memory recall, clinical dementia rating etc. that are required per diagnosis. The baseline diagnostic status is documented in the Diagnosis Summary Worksheet / eCRF (which may differ from the diagnosis status at screening captured in the ARM table).

ADNI GO the table name is DXSUM – Diagnostic Summary
Field is DXCHANGE - Which best describes the participant's change in
cognitive status from last visit to current visit?

The study clinician is responsible to re-assess diagnostic status at each in-clinic study visit and determine if a conversion or reversion to a new diagnostic category has occurred via the Diagnosis Summary Worksheet / eCRF.

ADNI GO the table name is DXSUM – Diagnostic Summary
Field is DXCHANGE - Which best describes the participant's change in
cognitive status from last visit to current visit?

Documentation to show support of conversion / reversion / or No Change is through the Diagnosis Summary – Baseline Changes Worksheet / eCRF

• ADNI GO the table name is BLCHANGE – Diagnostic Summary-Baseline Changes

NOTE: At the baseline visit only questions 13, 14, and 15 on the Diagnosis Summary-Baseline Changes form are administered. Questions 1-12 ask about change in performance on MMSE, ADAS etc. that do not apply at baseline. All subsequent visits after baseline, questions 1-15 are administered.

Diagnostic Summary

Baseline Changes Form	
Page 1 of 2	
Visit: EMCI Month 6	EVANUNATION DATE
ADNI PARTICIPANT NUMBER EXAMINER INITIALS	EXAMINATION DATE
	MONTH DAY YEAR
INSTRUCTIONS: This form should be completed by a physician	at every in-clinic visit to
confirm the participant's current diagnosis and	· · · · · · · · · · · · · · · · · · ·
has occurred. Please use the narrative summar	
information used to support the diagnosis.	,
Physician's Initials:	
Form Completed: MONTH DAY YEAR	
Dro visit Dinamosis:	
Pre-visit Diagnosis: □ NL □ MCI □ AD	
LINE LIMEI LAD	
 Clinically relevant worsening on ADAS? ☐ Yes ☐ No 	
2. Clinically relevant worsening on MMSE? ☐ Yes ☐ No	
3. Clinically relevant worsening on MMSE recall? \Box Yes \Box No	
4. Clinically relevant worsening on non-memory MMSE items? ☐ Yes ☐ No	
5. Clinically relevant worsening in memory on neuropsych testing \Box Yes \Box No	?
6. Clinically relevant impairment/worsening in non-memory cognitive \square Yes \square No	e domains on neuropsych testing?
7. Clinically relevant worsening in activities of daily living (FAQ)? ☐ Yes ☐ No	
8. Clinically relevant deterioration on CDR Sum of Boxes or Overal \Box Yes \Box No	I CDR rating?
9. Clinically relevant depression based on clinical judgement or GI \square Yes \square No	DS?

ADOS Diagnostic Summary	
Baseline Changes Form	
Page 2 of 2	
Visit: EMCI Month 6	
ADNI PARTICIPANT NUMBER	
10. Did subject have a stroke? ☐ Yes ☐ No	
11. Is there evidence of a delirium (medication effect, toxic or metabolic \Box Yes \Box No	encephalopathy)?
12. Has extenuating circumstance (such as a physical health problem, ch support network, death of a family member, etc.) contributed to a ch cognitive or functional performance?☐ Yes☐ No	_
If yes, describe:	
13. Is the change in clinical status corroborated by informant report of ch ☐ Yes ☐ No ☐ NA/No change in clinical status	nanges in ADL?
14. Is the change in clinical status corroborated by informant report of change in Clinical Status	nanges in cognition?
15. Narrative Summary:	



Diagnostic Summary

Page 1 of 4

Visit: EMCI Month 6

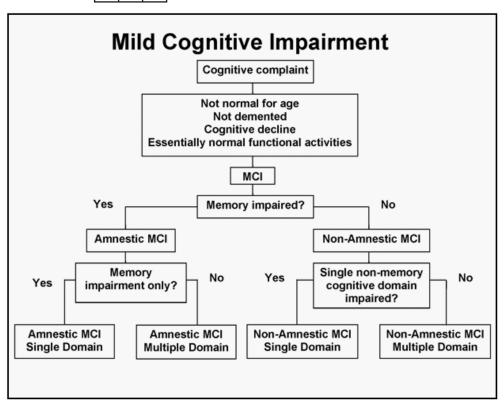
ADNI PARTICIPANT NUMBER	EXAMINER INITIALS	EXAMINA	TION DATE
		MONTH DAY	YEAR

INSTRUCTIONS:

This form should be completed by a physician at every in-clinic visit to confirm the participant's current diagnosis and whether a conversion has occurred. If the participant is currently MCI, please use the below chart to assist in making an assessment of whether the participant has MCI with memory features or non-memory features.

Date Form Completed: MONTH DAY YEAR

Clinician Initials:



1. Which best describes the participant's cognitive status from last visit to current visit:

Stable:	NL to NL
	MCI to MCI

☐ Stable: Dementia to Dementia

☐ Conversion: NL to MCI

☐ Conversion: MCI to Dementia☐ Conversion: NL to Dementia☐

 \square Reversion: MCI to NL

☐ Reversion: Dementia to MCI☐ Reversion: Dementia to NL

Alzheir	ner's Disease Cooperative Study
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AD@S
Diagnostic Summary
Page 2 of 4
Visit: EMCI Month 6
ADNI PARTICIPANT NUMBER
2. If growent status is MCI complete the following:
2. If current status is MCI, complete the following: 2a. MCI features (select all that apply):
☐ MCI - Memory features (amnestic)
☐ MCI - Non-memory features (non-amnestic)
If MCI - Memory features, complete the following (Petersen Criteria, see procedures manual for details):
i. Subjective memory complaint
Yes
□ No
ii. Informant memory complaint
Yes
□ No
iii. Normal general cognitive function
□ No
☐ Marginal
iv. Normal activities of daily living
☐ Yes
□ No
☐ Marginal
v. Objective memory impairment for age and education
☐ Yes ☐ No
vi. Not demented by diagnostic criteria
☐ Yes
□ No
2b. Suspected cause of MCI:
MCI due to Alzheimer's Disease
☐ MCI due to other etiology
If MCI due to other etiology, select box(es) to indicate reason:
☐ Fronto-temporal Dementia
☐ Parkinson's Disease
☐ Huntington's Disease
☐ Progressive Supranuclear Palsy
Alcoholic-related Dementia
□ NPH
☐ Major Depression
☐ Corticobasal Degeneration
☐ Vascular Dementia
☐ Prion-Associated Dementia ☐ HIV
☐ Primary Progressive Aphasia
☐ Posterior Cortical Dysfunction
☐ Other (Specify):

ADCS
Diagnostic Summary
Page 3 of 4
Visit: EMCI Month 6
ADNI PARTICIPANT NUMBER
3. If current diagnosis is dementia, complete the following:
3a. Dementia severity - clinician's impression
☐ Mild ☐ Moderate
□ Severe
3b. Suspected cause of dementia:
Dementia due to Alzheimer's Disease
☐ Dementia due to other etiology
If dementia due to Alzheimer's Disease, indicate likelihood:
☐ Probable
☐ Possible
If Possible AD, select box(es) to indicate reason:
Atypical clinical course or features (Specify):
☐ Stroke(s)
Depression
☐ Delirium
Parkinsonism
☐ Metabolic / Toxic Disorder (Specify):
☐ Other (Specify):
If dementia due to other etiology, select best diagnosis:
☐ Fronto-temporal Dementia
☐ Parkinson's Disease
☐ Huntington's Disease
☐ Progressive Supranuclear Palsy
☐ Alcoholic-related Dementia
□ NPH
☐ Major Depression
☐ Corticobasal Degeneration
☐ Vascular Dementia
☐ Prion-Associated Dementia
□ HIV
☐ Primary Progressive Aphasia
☐ Posterior Cortical Dysfunction

☐ Other (Specify): _____

Diagnostic Summary
Page 4 of 4
Visit: EMCI Month 6
ADNI PARTICIPANT NUMBER
4. Other conditions:
4a. Depressive Symptoms present?
☐ Yes
□ No
If yes, please describe:
4b. Parkinsonism symptoms present?
☐ Yes
□ No
If yes, please describe:

Baseline Symptoms Checklist was conducted only at the SCREENING visit to obtain a 'baseline' set of symptoms as being present or absent in order to have a benchmark to assess for potential adverse events at subsequent visits.

Diagnosis and Symptoms Checklist was conducted at all subsequent visits (and the list of symptoms/questions are identical to the Baseline Symptoms Checklist). If a new symptom was present (not noted at SCREENING on the Baseline Symptoms Checklist) OR if the condition noted at SCREENING had worsen in chronicity or severity it was to be documented as an adverse event.

			Packet Version	
Alzheimer's Disease Cooperative Study				
AD@5	Diag	gnosis and Symptoms Ched	cklist	
		Visit: EMCI Month 6		
ADNI PARTICIPAN	ΓNUMBER	EXAMINER INITIALS	EXAMINATION DATE	
s-[MONTH DAY YEAR	
Instructions: The Diagnosis and Symptoms Checklist is completed at each visit following the Screening Visit. Complete this with information from both the participant and study partner. If a diagnosis has been made, the diagnosis should be documented under "Other". Do not check symptoms associated with the diagnosis. Please review this checklist along with the Baseline Symptoms Log that was completed at screening. Any new condition/symptom since the screening visit should be reported as an Adverse Event on the AE Log. Additionally, any condition/symptom present at screening that has worsened in chronicity or severity will need to be captured as an Adverse Event on the AE Log and should be closed out on the Baseline Symptoms Log. Lastly, for any condition/symptom that was present at screening that has since resolved, please update the baseline symptom log to reflect this.				
Symptom	Absent Pres	ent Symptom	Absent Present	
1. Nausea	\vdash	18. Urinary frequenc	су Ц	
2. Vomiting		19. Ankle Swelling		
3. Diarrhea		20. Musculoskeletal	Ц Ц	
4. Constipation		21. Rash	Ц Ц	
5. Abdominal discomfort		22. Insomnia	\sqcup \sqcup	
6. Sweating		23. Depressed Mood		
7. Dizziness		24. Crying	\sqcup \sqcup	
8. Low energy		25. Elevated Mood	\sqcup \sqcup	
9. Drowsiness		26. Wandering	Ц Ц	
10. Blurred Vision		27. Fall		
11. Headache		28. Other Symptoms	s L	
12. Dry Mouth		Comments:		
13. Shortness of Breath		-	_	
14. Coughing				
15. Palpitations				
16. Chest pain				
17. Urinary Discomfort (e.g., burnir	ng) 📙 🔲			

			versio
Alzheimer's Disease Cooperative Study			
IADES	Rase	line Symptoms Checklist	
	Dasc	Visit: EMCI Screening	
ADNI PARTICIPAI	NT NI IMRER	EXAMINER INITIALS	EXAMINATION DATE
	T NOMBER		
			MONTH DAY YEAR
Log which is then r Episodic symptom: occurred during th	eviewed and updated at esseciated with medical	every visit. Complete this with information fro conditions listed on the Medical History form he screening visit. If a diagnosis has been made	present must be entered in the Baseline Symptor om both the participant and study partner. In should also be recorded on this form if they hav de, the diagnosis should be documented under
Symptom	Absent Present	Symptom	Absent Present
 Nausea Vomiting Diarrhea Constipation Abdominal discomfort Sweating Dizziness Low energy 		 18. Urinary frequency 19. Ankle Swelling 20. Musculoskeletal 21. Rash 22. Insomnia 23. Depressed Mood 24. Crying 25. Elevated Mood 	
9. Drowsiness		26. Wandering	
10. Blurred Vision		27. Fall	
11. Headache		28. Other Symptoms	
12. Dry Mouth		Comments:	
13. Shortness of Breath			
14. Coughing			
15. Palpitations			
16. Chest pain			
17 Urinary Discomfort (e.g. burn	ing)		

Version 6

Alzheimer's Disease Cooperative Study					box corresp update for E			st	
Baseline Symptoms Log									
	pa	age of			SC	BL	M 6 M 12	2	M 18
AI	ONI PARTICIPANT NUMBER	EXAMINER INIT		MINATION DATE DAY YEAR	_	_			
Instruction	At Screening record all symptoms marked Present on the Baseline Symptoms Checklist. At subsequent visits, the participant should be queried about the status of each symptom. Any new condition/symptom should be reported as an Adverse Event on the AE Log. Additionally, any condition/symptom present at screening that has worsened in chronicity or severity will need to be captured as an Adverse Event on the AE Log and should be closed out on the Baseline Symptoms Log. Lastly, for any condition/symptom that was present at screening that has since resolved, please update the baseline symptom log to reflect this.								
	No symptoms present a	at Screening Visit	1			 			CONT'G
SYMPTOM NUMBER	DESCRIPTION	SEVERITY	CHRONICITY	DATE OF ONSET		DA	ATE CEASED		AT FINAL FOLLOW UP
		1 Mild 2 Moderate 3 Severe	1 ☐ Single occurrence 2 ☐ Intermittent 3 ☐ Persistent	Month Day Year		Month Da	ay Year		
		1 Mild 2 Moderate 3 Severe	1 ☐ Single occurrence 2 ☐ Intermittent 3 ☐ Persistent	Month Day Year		Month Da	ay Year		
		1 Mild 2 Moderate 3 Severe	1 ☐ Single occurrence 2 ☐ Intermittent 3 ☐ Persistent	Month Day Year		Month Da	ay Year		
		1 Mild 2 Moderate 3 Severe	1 ☐ Single occurrence 2 ☐ Intermittent 3 ☐ Persistent	Month Day Year		Month Da	ay Year		
		1 Mild 2 Moderate 3 Severe	1 ☐ Single occurrence 2 ☐ Intermittent 3 ☐ Persistent	Month Day Year		Month Da	ay Year		
General C	Comments:								_

Versio
Alzheimer's Disease Cooperative Study ADOS Sample Collection: Clinical Labs
Visit: EMCI Screening
ADNI PARTICIPANT NUMBER EXAMINER INITIALS EXAMINATION DATE S -
ADNI GO PARTICIPANT
Instructions: Refer to the Procedures Manual for detailed instructions.
Test Review Date:
 3. Are there any clinically significant laboratory abnormalities that would exclude the participant from the study? NOTE: If Yes, participant may not be included in the study without an exception from the Project Director.
Clinician's Signature: Date:

Packet Version
Alzheimer's Disease Cooperative Study ADOS Sample Collection: Biomarker Samples
Page 1 of 4 Visit: EMCI Subjects Baseline
ADNI PARTICIPANT NUMBER EXAMINER INITIALS EXAMINATION DATE MONTH DAY YEAR
ADNI GO PARTICIPANT
Instructions: Begin by printing out a PDF of the online Biomarker Samples Form and completing the Sample Identification Labels. The bar code label must be placed on the transfer tube prior to freezing. Fluids should be collected in the following order:
 Biomarker plain red-top tubes (2 blood collection tubes) Biomarker lavender-top (2 blood collection tubes) CSF Collection(if applicable)
Complete the Biomarker Samples Form online before shipping samples. Include a copy of this worksheet with the shipment. FedEX all biomarker samples the SAME DAY on DRY ICE.
Please refer to the Procedures Manual for more detailed instructions.
This form must be completed ASAP once the FedEx information is available so that the UPENN lab can be notified of the shipment.
Which of the following was collected at this visit? Blood CSF None
Was CSF collected on a separate day from Blood Biomarkers?
MONTH DAY YEAR When CSF is collected on a separate date, enter data in the eCRF as a separate record.
If CSF collected, please answer the following: (ADNI Procedures recommend use of 22g Sprotte Needle with Gravity)
Needle Used:
Overnight fast from midnight?
The exact date and time entered below must be noted on the specimen labels. Date of Collection MONTH DAY YEAR Time of Collection :

CSF Collector Initials:

Phlebotomist Initials:

ADES				
Sample Collection: Biomarker Samples				
Page 2 of 4 Visit: EMCI Subjects Baseline				
	ADNI PARTICIPANT NUMBER			
	-s-			
2 Tubes of 10 ml PLAIN RED-TOP: S	erum Samples			
Time Collected	Amount Collected	Centrifuged Time		
HH: MM	mL	HH:MM		
Transfer Time	Volume of Serum Transferred	Time Frozen		
: HH: MM	mL	: HH: MM		
2 Tubes of 10 ml LAVENDER-TOP: P	lasma Samples			
Time Collected	Amount Collected	Centrifuged Time		
: HH : MM	mL	: HH : MM		
Transfer Time	Volume of Plasma Transferred	Time Frozen		
: HH : MM	mL	: HH : MM		
CSF				
Time Collected	Amount Collected	Transfer Time		
: HH : MM	mL	: HH: MM		
Volume of CSF Transferred	Time Frozen			
mL	: HH : MM			
Check if any of the following was per		Patch:		
☐ Lumbar Puncture Blood Pa ☐ Fluroscopy ☐ Lumbar Spine Film	tch MONTH DA	AY YEAR		
	ures was performed please complet	te the protocol deviation form and select		
Date of Fluoroscopy				
Month Day Year				
If Fluoroscopy performed, but no CS	F was collected, provide explanatio	on		

Sa	mple Collection	on: Biomark Page 3 of 4	ker Samples
		Cl Subjects Baselin	е
		RTICIPANT NUMBER	
		SHIII	
Date of Spine Film			
MONTH DAY	YEAR		
If Spine Film performed	l, but no CSF was collected	, provide explanatior	า:
FordForTranslation Normalism			
redex tracking Number	:		
Date FedExed			
MONTH DAY	YEAR		
Please review the follow was used for the visit th		cense plate numbers	to confirm that the appropriate label
Bas	eline	VST 2	200000 – 299999
Мо	nth 6	VST 3	300000 – 399999
Мо	nth 12	VST 4	400000 – 499999
Мо	nth 24	VST 6	600000 – 699999
Мо	nth 36	VST 7	700000 – 799999
Мо	nth 48	VST 8	800000 – 899999
Мо	nth 60	VST 9	900000 – 999999
Мо	nth 72	VST 10	1000000 – 1099999
Мо	nth 84	VST 11	1100000 – 1199999
License Plate Numbe from ADNI Barcode La		el) - see Procedures M	anual for further clarification

	Packet Version
. P	n: Biomarker Samples lage 4 of 4 Subjects Baseline
	TICIPANT NUMBER
	s — I I I
ENTER THE FOLLOWING FIELDS ONLINE USING "M	METHOD OF CSF COLLECTION" ECRF.
Was CSF collected? ☐ Yes ☐ No	
If No, please provide reason why the CSF was not col Illness Participant unavailable Participant unwilling Administrative problems Withdrawn consent Other (specify): Examination Date MONTH DAY YEAR	llected:
For CSF collected, please answer the following (ADN with gravity): Needle used:	I Procedures recommend use of 22g Sprotte Needle
☐ 18g Quincke (sharp bevelled) needle	☐ 18g Sprotte (atraumatic) needle
19g Quincke (sharp bevelled) needle	☐ 19g Sprotte (atraumatic) needle
20g Quincke (sharp bevelled) needle	20g Sprotte (atraumatic) needle
21g Quincke (sharp bevelled) needle	21g Sprotte (atraumatic) needle
22g Quincke (sharp bevelled) needle	22g Sprotte (atraumatic) needle
23g Quincke (sharp bevelled) needle	24g Sprotte (atraumatic) needle
24g Quincke (sharp bevelled) needle	
25g Quincke (sharp bevelled) needle	
Only Polypropylene tubes should be used for collect this is a protocol violation and must be noted in the	tion and shipment of CSF. If Polystyrene tubes are used, protocol deviations log.
Type of collection tube used: Polypropylene	Type of tube used for shipping: Polypropylene

Type of collection tube used:	Type of tube used for shipping:
Polypropylene	Polypropylene
Polystyrene (protocol violation)	Polystyrene (protocol violation

If collected in polystyrene and shipped in polypropylene, please provide estimated amount of time CSF

emained in collection tube.	
minutes	
LP performed at the:	Patient Position:

LP performed at the:	Patient Position:
☐ L3-L4 Interspace	☐ Sitting, leaned over (preferred
L2-L3 Interspace	Lying, curled up on side
□ ND/UNK	☐ ND/UNK

Al-la dina ada Dia ada	On any analysis Objects
Alzheimer's Disease	
San	nple Collection: ApoE/GWAS/RNA Genotyping
	Visit: EMCI Subjects Baseline
ADNI PA	ARTICIPANT NUMBER EXAMINER INITIALS EXAMINATION DATE
	HSH
	ADNI GO PARTICIPANT
Instructions:	Collect: 1 x 10 mL EDTA tube of whole blood for DNA sample collection. Collect: 3 x 2.5 mL PAXgene Blood RNA tubes of whole blood for RNA sample collection.
	If the PAXgene Blood RNA tube is the only tube to be drawn, a small amount of blood should be drawn into the 4.0mL serum discard tube (included in the RNA Blood Sample Kit) prior to drawing blood into the PAXgene Blood RNA tube. OTHERWISE, the PAXgene Blood RNA tubes should be the last tubes drawn in the phlebotomy procedure.
	The National Cell Repository must receive all whole blood samples within 24 hrs of collection. The whole blood samples must be maintained at room temperature and shipped by Federal Express - Priority Overnight (Monday-Thursday) at ambient temperature. NCRAD will not be able to accept any shipments on Saturday or Sunday. Please see the study procedure manual for directions when a lab draw is performed on Friday.
	Include a copy of this form in each shipment (keep original on site).
	DAY OF SHIPMENT: PLEASE FAX to (317) 278-1100.
	OR EMAIL A COPY OF THIS FORM TO NCRAD: alzstudy@iupui.edu
Year of Birth	Gender
Teal Of BITTI	☐ Male ☐ Female
Did the partici	pant give consent to DNA testing?
	pant give consent to store and share their DNA Sample?
	ble collected (1 x 10 mL purple top EDTA tube)? ☐ Yes ☐ No
	plete the following:
• Dai	te of DNA collection:
N	IONTH DAY YEAR
• Tim	ne of DNA collection (24hr clock):
	: HH:MM
• Phl	ebotomist Initials
Volume of bloo	od drawn into 10mL EDTA tube for DNA testing: mL
Date Fedexed:	
FedEx Tracking	Number:

Packet Version 3 Alzheimer's Disease Cooperative Study Sample Collection: ApoE/GWAS/RNA Genotyping Visit: EMCI Subjects Baseline **EXAMINER INITIALS EXAMINATION DATE** ADNI PARTICIPANT NUMBER S MONTH DAY YEAR ☐ Yes П No Did the participant give consent to RNA testing? No ☐ Yes П No Were the PAXgene Blood RNA tubes the last tubes drawn? If No, was a discard tube used? \square Yes \square No If yes, complete the following: • Date of RNA collection: Time of RNA collection (24hr clock): HH: MM **Phlebotomist Initials** Volume of blood drawn into 3 x 2.5 mL PAXgene RNA tubes: Was the same shipment date and Fedex tracking number used to ship the RNA sample? If No, please enter shipment date and Fedex tracking number. ☐ Yes ☐ No. Date Fedexed FedEx Tracking Number: _____ MONTH DAY YEAR Sample Collected and Sent By (print full name):

(Document any items to note regarding lab draw, packaging, or shipping. Please ensure these comments are

Phone and Email address:

entered in the "Visit Comment" eCRF for this visit)

Comments:

Alzheimer's Disease Cooperative Study ADOS
Sample Collection: Immortalization Cell Collection
Visit: EMCI Subjects Baseline
ADNI PARTICIPANT NUMBER EXAMINER INITIALS EXAMINATION DATE
ADNI GO PARTICIPANT
Instructions: Collect: 2 x 8.5 mL ACD-A tubes of whole blood for cell immortalization samples.
Did the participant give consent to DNA testing? Did the participant give consent to store and share their DNA Sample? Was cell immortalization sample collected? If yes, complete the following:
Phlebotomist Initials:
Date of cell immortalization collection:
Time of cell immortalization collection (24hr clock): HH: MM Date Fedexed: MONTH DAY YEAR
FedEx Tracking Number:
Total volume of blood drawn for Cell Immortalization into 2 x 8.5 mL ACD-A (yellow top tubes):
Sample Collected and Sent By (print full name):
Phone and Email address:
Comments: (Document any items to note regarding lab draw, packaging, or shipping. Please ensure these comments are entered in the "Visit Comment" eCRF for this visit)

Alzhein	ner's Disease Cooperative Study
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ADOS CSF - Local Lab Results
Visit: EMCI Subjects Baseline
ADNI PARTICIPANT NUMBER EXAMINER INITIALS EXAMINATION DATE MONTH DAY YEAR
Date of Sampling: Month Day Year
Time of Sample Collection : HH: MM
Time sent to Local Lab : HH: MM
White Blood Cell Count cells/microliter
Red Blood Cell Count cells/microliter
Protein Results (Round to the nearest whole number.) mg/dL
Glucose Results (Round to the nearest whole number.) mg/dL

84

Version 05/10/10

31 IVIRI Scan Information Page 1 of 4
Visit: EMCI Screening
ADNI PARTICIPANT NUMBER EXAMINER INITIALS EXAMINATION DATE
MONTH DAY YEAR
To be completed by Study Coordinator: Scheduled Date:
Study Coordinator Name:
Telephone #: L L L VEAR
ADNI Participant Initials:
To be completed by MRI Technologist (If section above is incomplete please contact study coordinator for subjection information):
NOTE: Every visit should have ORIGINAL scan data entered before any rescan data is entered.
Was the scan conducted? ☐ Yes ☐ No
If No, please provide reason why the scan was not conducted: ☐ Illness ☐ Participant unavailable ☐ Participant unwilling ☐ Administrative problems ☐ Withdrawn consent ☐ Other (specify):
Important: It is mandatory that the ADNI GO site qualified scanner be used for ALL participants in the ADNI GO study. It is also mandatory that the same ADNI GO approved sequences are used at all ADNI GO scans. Do NOT adjust protocol values. MRI Operator Initials Scan Date MONTH DAY MEAN MEAN
Please follow instructions in the ADNI Technical Manual for positioning the participant in the head coil.
Placed Stereotactic Marker on the patients (RT) temple? Yes No
Scan #1: Plane/Tri-Planar Scout (if available, otherwise use an axial scout): Check participant positioning in the head coil, reposition and re-scout if necessary.
Scout Completed?
Comments:
Scan #2: Straight Sagittal 3D MP-RAGE/IR-SPGR: DO NOT oblique the scanning FOV to compensate for subject held tilt. Position FOV to avoid nose wrapping into the back of the brain.
MP-RAGE – Completed?
Comments:

3T MRI Scan Information

31 IVIKI SCAN INTORMALION Page 2 of 4
Visit: EMCI Screening
ADNI PARTICIPANT NUMBER
Scan #3: Sagittal 3D Accelerated MP-RAGE/IR-SPGR: Please scan in the exact same position as the non-accelerated
scan unless repositioning is necessary. Repeat MP-RAGE – Completed?
Comments:
Confinents.
Complete only for Philips Systems: Scan #4: Axial Resting State fMRI (Subject should have eyes OPEN): Not a Philips
Was the subject instructed to open their eyes? \square Yes \square No
Did the subject keep their eyes open? (MRI Tech: ask the subject right after the scan)
The acquisition stack should be placed just above the most superior point in the brain and should cover inferior as much as possible, if the cerebellum is not covered fully, that is acceptable. Instruct the participant prior to this scan that they should have their eyes open and to hold very still. DO NOT oblique the scanning slices.
fMRI Completed? ☐ Yes ☐ No
Comments:
Scan #4: Axial FLAIR:
Position Slices to cover below cerebellum through the top of the head. DO NOT oblique the scanning slices.
FLAIR Completed?
Comments:
Scan #5: Axial T2 Star:
Position Slices to cover below cerebellum through the top of the head. DO NOT oblique the scanning slices.
T2 Star Completed? ☐ Yes ☐ No
Comments:

3T MRI Scan Information
Page 3 of 4
Visit: EMCI Screening ADNI PARTICIPANT NUMBER
Siemens Systems Only (with license agreement): Scan #6: Axial ASL Perfusion Scan (Subject should have eyes OPEN): Siemens Systems Only (with license agreement) Position Slices to cover below cerebellum through the top of the head. DO NOT oblique the scanning slices. Not a Siemens
Was the subject instructed to open their eyes? \square Yes \square No
Did the subject keep their eyes open? (MRI Tech: ask the subject right after the scan) \square Yes \square N
ASL Completed?
Comments:
Scan #6: Axial DTI Scan: GE Systems Only (with license agreement) Position Slices to cover below cerebellum through the top of the head. DO NOT obliq the scanning slices. Not a GE Systems DTI Completed?
Scan #7: Phantom QC Scan(s): Position Slices to completely cover the phantom. DO NOT oblique the scanning slices. ADNI phantom scan is required on the day of the ADNI GO subject scan (only one phantom scan is needed even if there are multiple subjects scanned on a single day.) Phantom Completed? Yes No (if No, Why not?)
Comments:
Patient Motion Problems:
Comments:

	CISIOI
Alzheimer's Disease Cooperative Study	
3T MRI Scan Information	
Page 4 of 4	
Visit: EMCI Screening	
ADNI PARTICIPANT NUMBER	
Scanner Malfunction:	
Comments:	
Other Protocol Variations:	
Comments:	
Was data transferred to LONI within 24 hours of scan?:	
☐ Yes ☐ No	
Transfer Date: MONTH DAY YEAR	
Comments:	
Data Archived Locally? (If No, please explain under comments.)	
Yes	
Archive Medium:	
☐ PACS ☐ CD/DVD	
□ мо р	
☐ No	
Comments:	
Comments.	
Was a Lumbar Puncture completed prior to the MRI scan? (To be completed by the Study Coordinator)	
Yes No	
If Yes, What was the interval between LP and MRI? I less than 6 hours I 13-24 hours 49-72 hours	
☐ 6-12 hours ☐ 25-48 hours ☐ more than 72 hours	
L 0 12 HOURS L 25 40 HOURS LIGHT / 2 HOURS	

Alzheimer's Disease Cooperative	
	FDG-Pet Scan Information Page 1 of 5
A DAU DA DITIOIDANI	Visit: EMCI Subjects Baseline T NUMBER EXAMINER INITIALS EXAMINATION DATE
ADNI PARTICIPANT	T NUMBER EXAMINER INITIALS EXAMINATION DATE MONTH DAY YEAR
To be completed by Stu	
Study Coordinator Name	:
· · · · · · · · · · · · · · · · · · ·	MONTH DAY YEAR
ADNI Participant Initials:	
☐ Illness ☐ Participa ☐ Participa ☐ Administ ☐ Withdrav	scan was not conducted: nt unavailable
Scan Date:	Technologist Initials
Month Day	Year
Select one of the followi	ng scanner vendors and models: Advance Discovery LS Discovery ST Discovery RX Discovery STE/VCT
☐ Siemens:	 □ ACCEL/EXACT □ Biograph (Model 1023/1024) □ Biograph HiRes (Model 1080) □ BioGraph TruePoint (Model 1093/1094) □ BioGraph mCT □ HR+ □ HRRT
☐ Phillips:	☐ Allegro ☐ Gemini ☐ Gemini - GXL ☐ Gemini - TF

ADOS
FDG-Pet Scan Information
Page 2 of 5
Visit: EMCI Subjects Baseline ADNI PARTICIPANT NUMBER
S - S - S - S - S - S - S - S - S - S -
Time of today's Scanner QC (Enter '00' for seconds portion of the time if seconds are unavailable.)
: HH:MM:SS Time of blood glucose measurement (Enter '00' for seconds portion of the time if seconds are unavailable.)
: HH:MM:SS Blood Glucose (pre-FDG) (<i>Proper Range:</i> < 180 mg/dL)
mg/dL
Time of FDG dose assay (Enter '00' for seconds portion of the time if seconds are unavailable.) HH:MM:SS FDC dose assay (Corrected for Residual Activity (Proper dose is 4.5., 5.5. mCi))
FDG dose assay [Corrected for Residual Activity (Proper dose is 4.5 - 5.5 mCi)] mCi
FDG Volume mL
Time of FDG injection (Enter '00' for seconds portion of the time if seconds are unavailable.)
: HH:MM:SS
Provide an explanation if blood glucose was measured after the FDG injection:
Emission Scan Start Time: Enter '00' for seconds portion of the time if seconds are unavailable. HH:MM:SS
Target start time is 30 min FDG post-injection. Provide an explanation if start time is not between 28 and 32 min post-injection.

FDG-Pet Scan Information Page 3 of 5

Visit:	<u>EMCI</u>	Sub	jects	Base	line

	adni pa	RTIC	IPANT	NUM	BER	
		S	H]
SECTION II. SCAN PROTOCOL INFORM	ΛΑΤΙΩΝ					
Any variations from protocol during FD Yes No If Yes, describe:	G uptake?					
Predefined Acquisition Protocol ID:						
Which framing rate was used? 6 frames, 5 min/frame (6x300s) 2 scans, 15 min each (2 x 900s) If any deviations, describe:	(only for B		•			
Subject motion problems: Yes No If Yes, decribe:						
Scanner malfunction Yes No If Yes, describe:						
Other protocol variations: Yes No If Yes, describe:						
SECTION III. SCAN RECONSTRUCTION Check which of the following reconstrut FORE/2D - OSEM (Siemens) OSEM3D (Siemens) (If HRRT scale) 3D Iterative (GE) 3D - Ramla (Philips) 3D Back-projection (GE)	ıctions was			se sel	ect OS	SEM3D)

FDG-Pet Scan Information

Page 4 of 5 Visit: EMCI Subjects Baseline
ADNI PARTICIPANT NUMBER
If FORE/2D-OSEM, OSEM3D, or 3D Iterative:
Subsets:
☐ 16
<u> </u>
☐ Other
If Other, specify:
Iterations:
☐ 6 ☐ Other
If Other, specify:
If 2D Damela misses somewhate either.
If 3D Ramla, please complete either: Lambda = (relaxation parameter)
OR OR
Was "Smooth" parameter set to "Sharp"? ☐ Check here to confirm
Check here to commit
If 3D Back-Projection, Ramp filter?
☐ Check here to confirm
If FORE/2D-OSEM select one of the following
Brain mode "ON" for PET-only Siemens scanners
☐ TRIM "ON" for PET/CT Siemens scanners (older software versions)☐ TRIM not available for PET/CT Siemens scanners (new software versions)
If TRIM not available, must reconstruct with a zoom of 2.0 into a 336x366 grid for BioGraph TruePoint
or 400x400 grid for BioGraph mCT
No post-process smoothing:
Check here to confirm
Attance tion Commention
Attenuation Correction:
Ge - 68 + Segmentation
☐ Cs - 137 + Segmentation



FDG-Pet Scan Information

Page 5 of 5

Visit:	<u>EMCI</u>	Subjects	Baseline

ADNI PARTICIPANT NUMBER						
		-[s]-				

SECTION IV. DATA TRANSFER AND ARCHIVE:

Was data transferred to LONI within 24 hours of scan?

Data must be transmitted to LONI within 24 hours of the PET scan. If your site is unable to complete the transfer with 24 hours please indicate the problem in the "Comments" section below.

☐ Yes
□ No
Transfer Date:
Month Day Year
Comments:
Was all raw PET data archived locally to be able to do complete reconstruction of PET Scan if needed? If No, please explain under comments Yes No
Archive Medium:
Comments:
SECTION V. LUMBAR PUNCTURE DATA: Was a Lumbar Puncture completed prior to the PET scan? Yes No
If Yes, what was the interval between LP and PET?
Less than 6 hours
☐ 6-12 hours
☐ 13-24 hours
☐ 25-48 hours
☐ 49-72 hours

☐ More than 72 hours

Alzheimer's Disease Cooperative Study									
ADOS									
AV-45 Pet Scan Information									
Page 1 of 5 Visit: EMCI Subjects Baseline									
ADNI PARTICIPAN	T NUMBER EXAMINER INITIALS EXAMINATION DATE								
	MONTH DAY YEAR								
To be completed by Stu	udy Coordinator: Scheduled Date:								
•	e:								
	MONTH DAY YEAR								
ADNI Participant Initials:									
☐ Illness ☐ Participa ☐ Participa ☐ Adminis ☐ Withdray	scan was not conducted: ant unavailable								
Scan Date:	Technologist Initials								
MONTH DAY	YEAR								
	ing scanner vendors and models:								
☐ GE:	 □ Advance □ Discovery LS □ Discovery ST □ Discovery RX □ Discovery STE/VCT 								
☐ Siemens:	 □ ACCEL/EXACT □ Biograph (Model 1023/1024) □ Biograph HiRes (Model 1080) □ BioGraph TruePoint (Model 1093/1094) □ BioGraph mCT □ HR+ □ HRRT 								
☐ Phillips:	☐ Allegro ☐ Gemini ☐ Gemini - GXL ☐ Gemini - TF								



ADES
AV-45 Pet Scan Information
Page 2 of 5
Visit: EMCI Subjects Baseline
ADNI PARTICIPANT NUMBER
Time of today's Scanner QC (Enter '00' for seconds portion of the time if seconds are unavailable.)
: HH:MM:SS
Time of AV-45 dose assay (Enter '00' for seconds portion of the time if seconds are unavailable.)
: HH:MM:SS
AV-45 dose assay [Corrected for Residual Activity (Proper dose is 8 - 10 mCi)]
mCi
AV-45 Volume
mL mL
Time of AV-45 injection (Enter '00' for seconds portion of the time if seconds are unavailable.)
: HH:MM:SS
Emission Scan Start Time: Enter '00' for seconds portion of the time if seconds are unavailable.
: HH:MM:SS
Target start time is 50 min AV-45 post-injection. Provide an explanation if start time is not between 48 and 52 min post-injection.

AV-45 Pet Scan Information						
Page 3 of 5						
Visit: EMCI Subjects Baseline ADNI PARTICIPANT NUMBER						
S - S - S - S - S - S - S - S - S - S -						
SECTION II. SCAN PROTOCOL INFORMATION						
Any variations from protocol during AV-45 uptake?						
Yes						
□ No						
If Yes, describe:						
Predefined Acquisition Protocol ID:						
Which framing rate was used?						
4 frames, 5 min/frame (4 x 300s)						
2 scans, 10 min each (2 x 600s) (only for BioGraph scanners without list-mode)						
If any deviations, describe:						
Subject motion problems:						
☐ Yes						
☐ No If Yes, decribe:						
ii res, decribe.						
Scanner malfunction						
Yes						
□ No						
If Yes, describe:						
Other protocol variations:						
☐ Yes						
□ No						
If Yes, describe:						
SECTION III. SCAN RECONSTRUCTION						
Check which of the following reconstructions was used:						
FORE/2D - OSEM (Siemens)						
OSEM3D (Siemens) (If HRRT scanners using OP, please select OSEM3D)						
☐ 3D Iterative (GE)						
3D - Ramla (Philips)						
3D Back-projection (GE)						

AV-45 Pet Scan Information

Visit: EMCI Subjects Baseline						
ADNI PARTICIPANT NUMBER						
If FORE/2D-OSEM, OSEM3D, or 3D Iterative:						
# Subsets:						
\square 16 \square 20						
Other						
If Other, specify:						
ii Other, specify.						
# Iterations:						
\square 4						
\square 6						
☐ Other						
If Other, specify:						
If 3D Ramla, please complete either: Lambda = (relaxation parameter) OR Was "Smooth" parameter set to "Sharp"? Check here to confirm						
If 3D Back-Projection, Ramp filter? Check here to confirm						
If FORE/2D - OSEM select one of the following Brain mode "ON" for PET-only Siemens scanners TRIM "ON" for PET/CT Siemens scanners (older software versions) TRIM not available for PET/CT Siemens scanners (new software versions) If TRIM not available, must reconstruct with a zoom of 2.0 into a 336x366 grid for BioGraph TruePoint or 400x400 grid for BioGraph mCT						
No post-process smoothing: Check here to confirm						
Attenuation Correction: CT Ge - 68 + Segmentation Cs - 137 + Segmentation						



AV-45 Pet Scan Information

Page 5 of 5
Visit: EMCI Subjects Baseline
ADNI PARTICIPANT NUMBER
SECTION IV. DATA TRANSFER AND ARCHIVE:
Was data transferred to LONI within 24 hours of scan?
Data must be transmitted to LONI within 24 hours of the PET scan. If your site is unable to complete the transfer with 24 hours please indicate the problem in the "Comments" section below.
☐ Yes
□ No
Transfer Date:
Month Day Year
Comments:
Was all raw PET data archived locally to be able to do complete reconstruction of PET Scan if needed?
If No, please explain under comments
☐ Yes
□ No
Archive Medium:

SECTION V. LUMBAR PUNCTURE DATA:

Vas (a Lı	umbar	Puncture	completed	prior to	the AV-	45 scan?

☐ Yes

Comments:

☐ No

If Yes, what was the interval between LP and AV-45?

☐ 6-12 hours

☐ 13-24 hours ☐ 25-48 hours

☐ 49-72 hours

☐ More than 72 hours

Alzheimer's Disease Cooperative Study
AV-45 Pre and Post Injection Vitals Form
Visit: EMCI Subjects Baseline
ADNI PARTICIPANT NUMBER EXAMINER INITIALS EXAMINATION DATE
MONTH DAY YEAR
Was scan conducted?
☐ Yes
□ No □ No □ □ □ □ □ □ □ □ □ □ □ □ □ □ □
AV-45 Scan date MONTH DAY YEAR
PRE-INJECTION VITALS: Vital signs will be taken in a supine position immediately prior to administration of AV-45 (within 5 minutes prior to injection).
Heart Rate: (bpm)
Respiration: (per min)
Blood Pressure: (systolic/diastolic)
Temperature:
Temperature Source:
Units: Farenheit
Celsius
POST-INJECTION VITALS: At the end of the imaging session prior to discharge (approximately 70 minutes
after AV-45 administration).
Heart Rate: (bpm)
Respiration: (per min)
Blood Pressure: (systolic/diastolic)
Temperature:
Temperature Source: Oral Tympanic Other
Units: Farenheit
Celsius
Name/Signature of person filling out form Date

The second secon	Packet Vers
Alzheimer's Disease Cooperative Study	
ADCS	
AV-45 24-48 Hour Follow-Up	
Visit: EMCI Subjects Baseline	
ADNI PARTICIPANT NUMBER EXAMINER INITIALS EXAMINATION S	DATE YEAR
Was 24-48 hours post imaging follow-up telephone contact made?	
Yes	
□ No	
☐ N/A - No AV-45 scan conducted	
If No, please comment:	
-	
If Yes, document below:	
Initials of staff who conducted telephone contact:	
· · · · · · · · · · · · · · · · · · ·	
Date of telephone contact:	
MONTH DAY YEAR	
Time of telephone contact:	
HH: MM	
Person who was contacted:	
☐ Participant	
☐ Study Partner	
Were any Adverse Events reported? ☐ Yes	
If any Adverse Events are reported, complete the AE eCRF page.	



Protocol Deviations Log Form
Page 2 of 2 Visit: EMCI Screening
ADNI PARTICIPANT NUMBER
THSHTT
If Inclusion/Exclusion Criteria: Item number (Only applicable to visits prior to Baseline)
Was IRB informed of Protocol Deviation?
☐ Yes
☐ No If yes, indicate date reported:
r yes, marcate date reported.
MONTH DAY YEAR
Have the rights, safety or well-being of participant been compromised?
☐ Yes
□ No
Description of Event (For Out of Window Baseline Visit, give the Screening Visit date and the scheduled Baseline
Visit date):

Version
Alzheimer's Disease Cooperative Study
Adverse Events and Hospitalizations - Log
Visit: EMCI Screening
ADNI PARTICIPANT NUMBER EXAMINER INITIALS EXAMINATION DATE
The following should be reported as Adverse Events: New symptoms Baseline symptoms that have worsened in chronicity or severity
If a diagnosis has been made, enter the diagnosis name under Event. Any symptoms associated with the diagnosis should be recorded in the Comments section of this form. Do not record associated symptoms as separate Adverse Events.
Adverse Event Number:
Medical term for event (enter diagnosis if possible):
Check here if: This symptom was reported on the Baseline Symptoms Checklist, but has worsened in chronicity or severity
Onset Date(If Month and/or Day are unknown, enter '' in their place. A valid year must be provided.) MONTH DAY YEAR
Estimated Onset Time: HH: MM 24 HOUR CLOCK
Is the event ongoing? ☐ Yes ☐ No
Cease Date (If Month and/or Day is unknown, enter '' in their place. A valid year must be provided. If Event is ongoing, leave Cease Date blank.)
MONTH DAY YEAR Chronicity:
☐ Single Occurrence ☐ Intermittent ☐ Persistent
Severity: Mild Moderate Severe

Version
Alzheimer's Disease Cooperative Study ADOS
Adverse Events and Hospitalizations - Log
Page 2 of 3
Visit: EMCI Screening
ADNI PARTICIPANT NUMBER
Was AE Serious? (If Yes, complete this form to the best of your ability within 24 hours. Refer to the Procedures Manual for further instructions on submission of SAEs.) ☐ Yes ☐ No Check here if:
☐ SAE prior to Baseline Visit
Serious Adverse Event Reported By:
Reason for Qualifying as Serious Adverse Event:
Life-Threatening? (If Yes, Serious must also be answered Yes.) Yes No Related to Imaging Procedure: Definitely Possibly Not Related
Related to Lumbar Puncture:
Definitely Possibly Not Related
Investigator Judgment of Relatedness to 18 F-AV-45 (NOTE: Only applicable within 48 hours of 18 F-AV-45 injection): \square Definitely \square Possibly \square Not Related
Concurrent Medication Prescribed or Changed (If Yes, update Concurrent Medications Log.) Yes No Did this event occur while the participant was being hospitalized for another event? Yes
 No If Yes, did this event prolong hospitalization? (If Yes, Serious must also be answered Yes.) ☐ Yes ☐ No
If No, did this event require hospitalization? (If Inpatient, Serious must be answered Yes. NOTE: All medications received during hospitalization must be reported on the Concurrent Medications Log.) No Yes - Outpatient Yes - Inpatient
If Outpatient, provide the date of visit: MONTH DAY YEAR

	version
Alzheimer's Disease Cooperative Study ADOS Adverse Events and Hospitalizations - Log Page 3 of 3	
Visit: EMCI Screening	
ADNI PARTICIPANT NUMBER	
If hospitalized, Admission Date:	
Admit Diagnosis:	
Discharge Date : MONTH DAY YEAR Discharge Diagnosis:	
Did this event result in death? (If Yes, Serious must also be answered Yes.): ☐ Yes ☐ No	
Date of death: MONTH DAY YEAR	
Cause of death:	
Was diagnosis of Alzheimer's confirmed at autopsy? No Yes No postmortem brain exam	
Comments (Use comments section to clarify vague or problematic symptoms such as dizziness, chest pain, abdominal discomfort or the circumstances surrounding falls and trauma. If the circumstances of a fall or trau reveal additional AEs or symptoms such as light-headedness, poor balance, visual disturbance, etc., record the additional AEs and briefly describe the scenario in the comments section under one of the related symptoms):	
Clinician's Signature (required) Date	

Alzheimer's Disease Neuroimaging Initiative Grand Opportunity ADNI GO

Cognitive Assessments

The information in this document is privileged or confidential and is the property of ADCS. Persons to whom the information is disclosed must be informed that the information is privileged or confidential.

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SCREEN:

Psychometric Testing:
☐ MMSE
Logical Memory I
☐ Instructional Page
Logical Memory II (30-40 minute delay)
Eogleanmentory in (50 40 minute delay)
BASELINE:
Neuropsychological Testing Order of Assessments:
ADAS Cog Word List 1
ADAS-Cog Word List 1
Everyday Cognition - Participant Self-Report Everyday Cognition - Study Partner Report
Rey Auditory Verbal Learning Test (Trials 1-6)
Clock Drawing
Clock Drawing Category Fluency (animals) Trails A & B
☐ Trails A & B
Boston Naming Test (30 items)
Rey Auditory Verbal Learning Test (30 minute Delay)
MONTH
MONTH 6:
Neuropsychological Testing Order of Assessments:
ADAS-Cog (Word Recall List 2)
Rey Auditory Verbal Learning Test (Trials 1-6) Version B
☐ Montreal Cognitive Assessment (MoCA)
☐ Clock Drawing
Category Fluency (animals)
☐ Trail Making Tests A & B
Boston Naming Test (30 items)
Rev Auditory Verbal Learning Test (30 minute Delay) Version B.

MONTH 12:

Neurop	sychological Testing Order of Assessments:
	ADAS-Cog (Word Recall List 1)
	MMSE
	Logical Memory I
	Rey Auditory Verbal Learning Test (Trials 1-6) Version A
	Montreal Cognitive Assessment (MoCA)
	Clock Drawing
	Category Fluency (animals)
	Trails Making Test A & B
	Boston Naming Test (30 items)
	Logical Memory II
	Rey Auditory Verbal Learning Test (30 minute Delay) Version A

Cognitive Assessment Placeholder due to Copyright Restrictions

MMSE: Due to copyright restrictions, the MMSE is not included in the worksheet packet. For a copy of the MMSE please contact PAR (http://www4.parinc.com/Default.aspx).

Word list - Apple, Penny, Table was used for the immediate and delayed recall at all study visits where MMSE was administered. For the attention section – spelling 'world' backwards was administered but not counting backwards from 100.

Logical Memory and Digit Span (forward/backward): Due to copyright restrictions, these assessments are not included in the worksheet packet. Wechsler D. Wechsler Memory Scale-Revised. San Antonio, Texas: Psychological Corporation; 1987. For copy of these assessments please contact Pearson (http://www.pearsonclinical.com/education.html)

Logical Memory: Version A – Anna Thompson story was used at all study visits where LM was administered. The Logical Memory II -Delayed Recall was administered at least 30 and no more than 40 minutes after this Logical Memory I – Immediate Recall.

Boston Naming Task: For ADNI, only the odd-numbered items from the full test were administered.

American National Adult Reading Test							
Page 1 of 2							
ADN	JI PARTIC	IPANT N		MCI Subjects Baseline EXAMINER INITIALS EXAMINATION DATE			
	- s	7		MONTH DAY YEAR			
Instructions: Present the subject with the word list (not the tester's worksheet) and say, "I would like you							
to read a list of words aloud. Some of the words may be unfamiliar and difficult to pronounce, but do the best you can to pronounce them."							
CORRECT INCORRECT							
CORRECT		1.	ache	ĀK			
		2.	debt	DET			
		3.	pint	PĪNT			
		4.	depot	DĒ po			
		5.	chord	KORD			
		6.	bouquet	bō KĀ ; bü KĀ			
		7.	deny	di NĪ			
		8.	capon	KĀ pon			
		9.	heir	ÂR			
		10.	aisle	ĪL			
		11.	subtle	SU tl			
		12.	nausea	NÔ zē 9 ; NO sē9 ; NO sh9			
		13.	gauge	GĀJ			
		14.	naive	nä ĒV			
		15.	thyme	TĪM			
		16.	courteous	KəR tē əs			
		17.	algae	AL jē			
		18.	fetal	FĒ tl			
		19.	quadruped	KWOD roo ped; KWOD rə ped			
		20.	epitome	i PIT ə mē ; ə PID ə mē			
		21.	superfluous	soo PəR floo əs ; sü PəR floo əs			
		22.	chamois	SHA mē			
		23.	papyrus	pə PĪ rə s			
		24.	asthma	AZ mə			
	П	25	hiatus	hī Ā təs			

ADOS American National Adult Reading Test					
Page 2 of 2 Visit: EMCI Subjects Baseline					
			ADNI PARTICIF	•	
CORRECT	CORRECT INCORRECT				
		26.	simile	SI me lē	
		27.	blatant	BLĀ tent	
		28.	cellist	CHE list	
		29.	zealot	ZE let	
		30.	abstemious	ab STĒ me əs	
		31.	meringue	m9 RANG	
		32.	placebo	plə ${f S}ar{{f E}}$ bō	
		33.	facade	fə SAD	
		34.	pugilist	PYOO ja list	
		35.	virulent	VIR ye lent; VIR e lent	
		36.	worsted	WOOS tid; WeR stid	
		37.	detente	dā TANT	
		38.	anise	AN is	
		39.	sieve	SIV	
		40.	chassis	SHA sē; CHA sē	
		41.	beatify	īð e TA j	
		42.	scion	SI en	
		43.	cabal	ke BAL	
		44.	apropos	a prə PŌ	
		45.	caprice	kə PRĒS	
		46.	demesne	di MĀN ; di MĒN	
		47.	imbroglio	im BRŌ L yō	
		48.	hyperbole	hī PəR bə lē	
		49.	syncope	SIN kə pē ; SING kə pē	
		50.	prelate	PREL it; PREL ət	
Total Number of Errors (grand total from page 1 and page 2):					

ADNI GO Specific Version 05/10/10

ache gauge

debt naive

pint thyme

depot courteous

chord algae

bouquet fetal

deny quadruped

capon epitome

heir superfluous

aisle chamois

subtle papyrus

nausea asthma

hiatus anise

simile sieve

blatant chassis

cellist beatify

zealot scion

abstemious cabal

meringue apropos

placebo caprice

facade demesne

pugilist imbroglio

virulent hyperbole

worsted syncope

detente prelate

Testing Comments: _____



ADAS Cognitive Behavior

		Page 1 of 11			
		MCI Subjects Base			
ADNI PARTICIPANT N	EXAMI	NATION DATE	_		
			MONTH DAY	YEAR	
ADAS Initial Conversation	Notes				
For specific instruction conversation in order cognitive tests are adrespecific tests. Question questions should requestions should requestions should requestion at the participant of the put the participant at observe how well the language ability on the Documentation should word Finding Difficult supported by notes definition of the converse of the process of th	to assess various as ministered. Languars eliciting "yes" and uire specific information a short converse clinic, or what the ease before the test participant can use the cognitive part of ld be evident on that (Item 11) and Core	spects of expressive ge abilities are evalued "no" answers assessation and well-develosation about neutral e participant had for sting begins and will e and understand lare the ADAS. Use this participant (Item 12 mprehension (Item 12 mprehension)	and receptive speech ated throughout the scomprehension on oped communicatio topics (for example: breakfast). This convigive the examiner an guage. There are the page to record your iting of Spoken Lang	n. Then the remain interview and on a very basic level. In skills. weather, the versation will help in opportunity to ree clinical ratings interview notes. uage Ability (Item	ing Other to of
Possible Topics:	Appetite	Sleep	Exercise	Other	
1) Comprehension					
2) Spoken Language					
3) Word Finding					



ADAS Cognitive Behavior

Page 2 of 11 Visit: EMCI Subjects Baseline

ADNI PARTICIPANT NUMBER						

1. Word-recall (Word Recall List 1)

To begin testing, say: "I am going to show you some words printed on these white cards. Please read each word out loud and try to remember it, because later I will ask you to try to remember all of the words I have shown you. Ready, read the word and try to remember it."

Present each word to the participant and ask him/her to say it aloud. After all 10 words have been presented, say: "Good, now tell me all the words you can remember that were on that list." Prompt with "Any others?" as necessary. For trials 2 and 3 say: "Now I am going to show you that same list again. Read each word out loud and try to remember it." Examiner should check "yes" for every word recalled correctly.

Word Recalled?

Trial 1	Yes
1. BUTTER	
2. ARM	
3. SHORE	
4. LETTER	
5. QUEEN	
6. CABIN	
7. POLE	
8. TICKET	
9. GRASS	
10. ENGINE	
Total:	

Word Recalled?

Trial 2	Yes
1. POLE	
2. LETTER	
3. BUTTER	
4. QUEEN	
5. ARM	
6. SHORE	
7. GRASS	
8. CABIN	
9. TICKET	
10. ENGINE	
Total:	

Word Recalled?

•	
Trial 3	Yes
1. SHORE	
2. LETTER	
3. ARM	
4. CABIN	
5. POLE	
6. TICKET	
7. ENGINE	
8. GRASS	
9. BUTTER	
10. QUEEN	
Total:	

TIME ENDED (24hr clock):

If any word-recall trial not administered, check one:

Ш	Not done (for reasons other than physical/cognitive).
	Participant refused.

Participant unable to complete 3 trials for cognitive reasons.



ADAS Cognitive Behavior

	ADAS COGINAVO				
	Page 3 of 11				
	Visit: EMCI Subjects Baseline				
	ADNI PARTICIPANT NUMBER				
2.	Commands				
	This item is designed to assess receptive speech. The participant is asked to carry out five se commands with 1 to 5 steps per command. Each command should be read once. If the participant respond or looks confused, or asks for a repetition, the examiner should give the ENTIRI one more time. Then go on to the next command. All commands should be given to every participant is asked to carry out five seecond or looks confused, or asks for a repetition, the examiner should give the ENTIRI one more time. Then go on to the next command. All commands should be given to every participant is asked to carry out five seecond or carry out fi	icipant E comn	nand		
	Response correct?				
		Yes	No		
a.	"Make a fist."				
b.	"Point to the ceiling, and then to the floor."				
	Line up a pencil, watch and card (in that order) on the table.				
c.	"Put the pencil on top of the card and then put it back."				
d.	"Put the watch on the other side of the pencil and then turn over the card."				
e.	"Tap each shoulder twice with two fingers, keeping your eyes shut."				

If task not administered, check one:

ш	Not done (for	reasons other	than p	nysicai/cd	gnitive).
---	---------------	---------------	--------	------------	-----------

- Participant refused.
- Participant unable for physical reasons.
- Participant unable for cognitive reasons.

ADAS Cognitive Behavior

Page 4 of 11
Visit: EMCI Subjects Baseline
ADNI PARTICIPANT NUMBER

3. Constructional Praxis

This test assesses the participant's ability to copy 4 geometric shapes. The shapes should be presented one at a time. If the participant looks confused or dissatisfied with the drawing, or asks to try again, the participant should be allowed *a second attempt* for each shape. If a second attempt is made, ask the participant to indicate which one is better, and score only that attempt.

To begin testing, say: "On this piece of paper is a shape. Try to draw another one that looks just like this, somewhere on the page."

Instructions: Please check the appropriate response for each shape. Please note, in a "recognizable attempt", the attempt should show at least one line that might represent a side or portion of the shape

- a. Circle: A closed curved shape.Shape drawn incorrectly.
 - ☐ Shape drawn incorrectly (at least one side/section of shape drawn).☐ No recognizable attempt at drawing any side/section of shape
- **b.** Two overlapping rectangles: Each shape must be four-sided and overlap must be similar to presented diagram.

Shape drawn correctly.

- Shape drawn incorrectly (at least one side/section of shape drawn).
- $\ \square$ No recognizable attempt at drawing any side/section of shape
- **c. Rhombus (Diamond):** Shape must be four-sided, oriented so that the points are at the top and bottom, and the sides approximately equal in length (e.g., longest side is not > 1.5 times the length of the shortest side).

☐ Shape drawn correctly.

- Shape drawn incorrectly (at least one side/section of shape drawn).
- ☐ No recognizable attempt at drawing any side/section of shape
- **d. Cube:** The shape is 3-dimensional, with front face in the correct orientation, internal lines drawn correctly between corners. Opposite sides of faces should be approximately parallel.

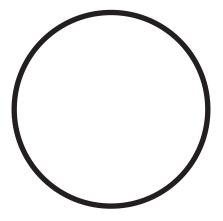
 \square Shape drawn correctly.

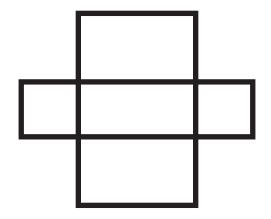
- Shape drawn incorrectly (at least one side/section of shape drawn).
- ☐ No recognizable attempt at drawing any side/section of shape

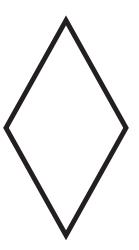
If task not administered, check one:

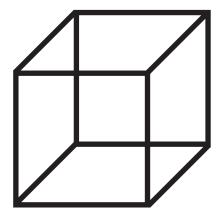
Not done (for reasons other than physical/cognitive).
Participant refused.
Participant unable for physical reasons.

Participant unable for cognitive reasons.









Alzheimer's Disease Cooperative Study			Packet Version
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	NI PARTICIPAI		
	s		
TIME BEGAN (24hr clock):	HH: M	М	
4. Delayed Word-recall task (Word Recall Lis Ask the participant to recall as many Word Recall task.		sible from	the words presented in the Immediate
to word list) Tell me all of the words	you can rem no response	ember th or if the p	ome words printed on these cards. (point nat were on the cards." Prompt with "Any participant indicates he/she cannot recall any word recalled correctly.
	Wo	rd Recalled?	,
	Trial 1	Yes	
	1. BUTTER		
	2. ARM		
	3. SHORE		
	4. LETTER		
	5. QUEEN		
	6. CABIN		
	7. POLE		
	8. TICKET		
	9. GRASS		
	10. ENGINE		
	Total:		
If trial not administered, check one: Not done (for reasons other than phy	vsical/cogniti	/e).	

ADNI GO Specific Version 03/04/11 22

☐ Participant refused.

☐ Participant unable cognitive reasons.

Alzheimer's Disease Cooperative	Study



Visit: EMCI Subjects Baseline	
ADNI PARTICIPANT NUMBER	

5. Naming Objects / Fingers

In 5A, the participant is asked to name 12 randomly presented real objects. Objects should be presented in random order. Give the participant instructions similar to the following: "Now I am going to show you some objects. I want you to tell me what their names are. What is this called?" (present object). If the participant responds with the object's function say: "Yes, that's what it does, but what is its name?" If the participant does not respond, the examiner should give the semantic cue for that item (provided below). If the participant still does not respond or makes an error, proceed to the next object. Examiner should check a response (yes/no) for every object/finger.

Response correct?

5A: Object Names - (Semantic Cues)	Yes	No
Flower - (grows in a garden)		
Bed - (used for sleeping)		
Whistle - (makes a sound when you blow on it)		
Pencil - (used for writing)		
Rattle - (a baby's toy)		
Mask - (hides your face)		
Scissors - (cuts paper)		
Comb - (used on hair)		
Wallet - (holds your money)		
Harmonica - (a musical instrument)		
Stethoscope - (doctors use it to listen to your heart)		
Tongs - (picks up food)		

In 5B, the participant is asked to name the fingers on his/her dominant hand. Say: "Please place your right (or left) hand on the table. Now I am going to point to a part of your hand and I want you to tell me what it is called. What is this finger called?"

	Response	correct
5B: Fingers	Yes	No
Thumb		
Middle		
Ring		
Index/Pointer		
Pinky		

If task not administered, check one:

	Not done (for reasons other than physical/cognitive)).
_		

☐ Participant refused.

	Participant unable fo	r cognitive reasons
--	-----------------------	---------------------



ADAS Cognitive Behavior

Page 7 of 11 Visit: EMCI Subjects Baseline

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6. Ideational Praxis

This item is designed to determine whether the participant can perform a familiar but complex sequence of actions. There are 5 tasks to this item. Place a long envelope, an $8\frac{1}{2}$ "×11" sheet of paper and a pencil in front of the participant.

Give the participant the following instructions: "I want you to pretend you have written yourself a letter. Take this piece of paper, fold it so that it will fit into the envelope, and then put it into the envelope. Then, seal the envelope, address the envelope to yourself, and show me where the stamp goes."

If the participant forgets part of the task, or is having difficulty, the examiner should repeat the instruction for the task where the participant is having difficulty. After the complete instruction is given, only ONE additional reminder should be given for each task. *Examiner should check a response (yes/no) for every task.*

Task		Action c	orrect? No
a.	Fold the paper		
b.	Put the paper in the envelope		
c.	Seal the envelope		
d.	Address the envelope to yourself		
e.	Show me where the stamp goes		
If t	ask not administered, check one: Not done (for reasons other than physical/cognitive). Participant refused. Participant unable for physical reasons. Participant unable for cognitive reasons.		



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ADAS Cognitive Behavior		
Page 8 of 11		
Visit: EMCI Subjects Baseline		
ADNI PARTICIPANT NUMBER		
 7. Orientation This item is designed to determine how well oriented the participant is with regard to a Ask the participant for each of these pieces of information one at a time. One restatent question is allowed(e.g., if participant confuses day and date.) Examiner should check a every question. Ref a. Full name (must be exact) b. Month (must be exact) 	nent of ea	ch (yes/no) for
c. Date (± 1 day)	Ħ	ī
d. Year (must be exact)		
e. Day of the week (must be exact)		
f. Season (within 1 week of upcoming season or within 2 weeks of previous season)		
g. Place (partial names are acceptable, but generic terms are not)		
(Say: "Where are we now?" or "What is the name of this place?")		
h. Clock Time (± 1 hour) (Say: "Without looking at your watch, tell me approximately what time it is.")		
If task not administered, check one: Not done (for reasons other than physical/cognitive).		
Participant refused.		
Participant unable for cognitive reasons.		



ADAS Cognitive Behavior

Page 9 of 11 Visit: EMCI Subjects Baseline

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8. Word Recognition (List 1)

In the learning portion of this test, the participant is given one trial to learn a list of 12 words. (See procedures manual for instructions on using the stimulus cards.) Say: "I am going to show you some words printed on these white cards. I want you to read each word out loud and try to remember it."

In the recognition portion of this test, the examiner should say: "Now I'm going to show you another set of words. Some of the words were on the list I just showed you and others are new. For each word I want you to tell me whether it is one of the words I just showed you."

The examiner shows the first word and says either "Is this one of the words I showed you before, yes or no?", or "Did I show you this word before?" The same instruction is given before the second test word. For the remaining test words the examiner should say: "How about this one?" or "Just take your best guess."

Check the **participant's response** to each word **Yes** or **No**. If the participant needs to be reminded of the task during the exam, the examiner should repeat the question and place a check in the reminder column.

Check participant response

	16	sponse	
Word	Yes	No	*R
1. Nurse			
2. Magazine			
3. Wizard			
4. Van			
5. Leopard			
6. Sale			
7. Sea			
8. Train			
9. Coin			
10. Ship			
11. Institution			
12. Map			
13. Axe			
14. Board			
15. Carrot			
16. Milk			
17. Volume			
18. Forest			
19. Anchor			
20. Gem			
21. Cat			
22. Fund			
23. Edge			
24. Cake			

*R = Reminder given

If task i	not administered, check one:
	Not done (for reasons other than physical/cognitive).
	Participant refused.

ADAS Cognitive Behavior

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	Page 10 of 11 Visit: EMCI Subjects Baseline
	ADNI PARTICIPANT NUMBER
9.	Remembering Test Instructions (based only on observations during Word Recognition task): This item evaluates the participant's ability to remember the requirements of the Word Recognition task. The number of reminders given on the Word Recognition task are counted to rate this item. If the Word Recognition task was not completed or not attempted, then this item must not be scored. Each instance of memory failure for the test instructions after the first two items is scored. None - participant never needs extra reminders of instructions Very mild - forgets once Mild - must be reminded 2 times Moderate - must be reminded 3 or 4 times Moderately severe - must be reminded 5 or 6 times Severe - must be reminded 7 or more times
	Severe - must be reminded / or more times
10.	Comprehension: This item evaluates the participant's ability to understand speech. To rate this item the examiner should consider how well the participant was able to understand the examiner's speech during the opening discussion and during the test session. Do not include responses to commands. None - no evidence of poor comprehension Very mild - one or two instances of misunderstanding Mild - 3-5 instances of misunderstanding Moderate - requires several repetitions and rephrasing
	 ■ Moderately severe - participant only occasionally responds correctly; i.e., yes/no questions ■ Severe - participant rarely responds to questions appropriately, not due to poverty of speech
11.	Word Finding Difficulty: To rate this item, the examiner must determine whether the participant has difficulty in finding the desired word in spontaneous speech during the interview and test session. Do not include finger and object naming in this rating. Documentation should be evident on Page 1 to support any rating above zero. (Refer to the procedures manual for guidelines)
	☐ None - no evidence of word finding difficulty in spontaneous speech
	☐ Very mild - 1 or 2 instances, not clinically significant
	☐ Mild - noticeable circumlocution or synonym substitution
	☐ Moderate - loss of words without compensation on occasion
	☐ Moderately severe - frequent loss of words without compensation
	Severe - nearly total loss of content of words; speech sounds empty; 1-2 word utterances

\frown	ADAS Cognitive Behavior						
	Page 11 of 11						
	Visit: EMCI Subjects Baseline						
	ADNI PARTICIPANT NUMBER						
12.	Spoken Language Ability: This item is a global rating of the quality of speech, i.e., clarity, difficulty in making oneself understood. In rating this item the examiner should consider all of the speech produced by the participant in the initial interview and the test session. Documentation should be evident on Page 1 to support any rating above zero. (Refer to the procedures manual for guidelines)						
	None - no instances where it is difficult to understand the participant						
	☐ Very mild - one instance of lack of understandability						
	☐ Mild - participant has difficulty less than 25% of the time						
	☐ Moderate - participant has difficulty 25-50% of the time						
	☐ Moderately severe - participant has difficulty 50% of the time						
	Severe - one or two word utterance; fluent, but empty speech; mute						
	Instructions for Example: Place the practice form face up in front of the participant. Say, "On the top of this page are two numbers. Throughout this page you will find these numbers mixed in with other numbers. I'd like you to begin here" (point to the beginning of the first line) "and going across line by line, cross off each number that matches either of the two numbers at the top of the page. Please work as quickly as you can." Discontinue the example after 30 seconds. Instructions for Task: Place the form face up in front of the participant and say: "On the top of this page are two numbers. Throughout this page you will find these numbers mixed in with other numbers. I'd like you to begin here" (point to the beginning of the first line), "and going across line by line,						
	cross off the numbers that match the numbers at the top of the page. Please work as quickly as you can."						
	If the first cancellation done by the participant is incorrect, say: " These are the correct numbers to cross out, " and point to the target numbers at the top of the page. If the participant becomes confused or stops while doing the test, repeat the standard instructions as needed. Discontinue the test after <u>45</u> seconds.						
	13a. Number Cancellation: Number of targets hit						
	13b. Number Cancellation: Number of errors						
	13c. Number Cancellation: Number of times reminded of task						
	If Number Cancellation Task not administered, check one: ☐ Not done (for reasons other than physical/cognitive). ☐ Participant refused. ☐ Participant unable for physical reasons. ☐ Participant unable for cognitive reasons.						

"6" and "1"

1 2 2 4 5 9 5 6 6 9 1 9 6 7 8 3 2 4 3 7 2 1 4 2 2 1 2 6 6 3

6 2 6 7 2 3 1 3 8 5 5 5 8 1 7 9 1 7 2 7 4 5 7 6 1 3 9 6 2 1 9 4 6 9 5 7 1 8 9 5 6 5 4 2 7 1 5 2 7 9 1 7 1 1 1 4 2 8 5 8 1 9 7 9 7 1 6 7 8 6 5 5 7 2 9 6 5 9 5 4 7 3 2 4 5 6 1 4 3 4 4 6 8 4 1 4 1 7 2 4 7 1 7 6 7 5 4 9 8 7 5 6 2 1 6 9 3 1 4 8 8 6 7 1 7 1 3 4 3 9 8 6 5 1 8 3 4 2 6 9 9 6 1 6 4 3 9 3 4 4 9 3 8 7 2 5 4 4 8 7 6 4 1 4 7 2 6 8 7 5 6 3 2 6 4 4 6 8 4 8 3 4 7 5 4 4 7 9 7 3 6 8 6 5 4 7 4 3 4 9 2 5 3 5 4 7 3 5 4 9 3 3 8 1 8 4 2 6 5 6 6 1 7 2 4 2 9 7 9 7 6 1 5 1 4 1 9 8

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Auditory Verbal Learning Test (A.V.L.T.) Immediate - Version A

ADNI PARTICIPANT NUMBER EXAMINER INITIALS EXAMINATION DATE

MONTH DAY YEAR

Trial 1 Instruction:

Say, "I am going to read a list of words. Listen carefully, for when I stop you are to repeat back as many words as you can remember. It doesn't matter in what order you repeat them, just try to remember as many as you can."

Trial 2-5 Instructions:

Say, "Now I am going to read the same words again, and once again when I stop I want you to tell me as many words as you can remember, including words you said the first time. It doesn't matter in what order you say them, just as many words as you can remember, whether or not you said them before."

List B Instructions:

Say, "Now I'm going to read a second list of words. Listen carefully, for when I stop you are to repeat back as many words as you can remember. It doesn't matter in what order you repeat them, just try to remember as many as you can."

Trial 6 Instructions:

Say, "Now tell me all the words you can remember from the first list, the list I repeated a number of times."

List						AFTER B-RECALL	List	List B
Α	1	2	3	4	5	6	В	Recall
Drum					ĺ		Desk	
Curtain							Ranger	
Bell							Bird	
Coffee							Shoe	
School							Stove	
Parent							Mountain	
Moon							Glasses	
Garden							Towel	
Hat							Cloud	
Farmer							Boat	
Nose							Lamb	
Turkey							Gun	
Color							Pencil	
House							Church	
River							Fish	
Totals								
Intrusions								

Instructions: Begin delay task 30 minutes from completion of List B Recall.



AD©S MoCA Administration Instructions
Visit: EMCI Subjects Baseline
ADNI PARTICIPANT NUMBER EXAMINER INITIALS EXAMINATION DATE
Indicate with a checkmark in the box underneath each portion of the test only if the subject completed the task correctly. Enter the score for each individual task into the eCRF. No section scores or total score are required for ADNI.
Record verbatim responses so that scoring can be re-checked by the clinical monitor.
For Cube and Clock, the subject may be allowed to use an area other than those provided on the MoCA test sheet to reproduce the items (e.g. an additional blank page, with subject ID and visit date indicated).
Attention Section: Digits: Score as correct only if the entire string of numbers is repeated correctly.
List of Letters/Tapping: record the number of errors by the subject (i.e. either a tap on a wrong letter, or failure to tap on an A) by circling any incorrect responses.
Serial 7 subtraction: Record subject's verbatim response and score based on subtraction from prior number. Example: If a subject gives an incorrect response, then subsequently correctly subtracts 7 from that number, this is a correct response.
Language Section: → Fluency: Record the number of words correctly named by the subject. Use the worksheet provided to write out the subject's verbatim responses.
For additional administration and scoring instructions on the MoCA, please reference the ADNI GO Procedures Manual.

Begin (4)		Copy cube	Draw CLOCK (3 points)	(Ten past eleve	n)	
	3)					
	1	[]	[] Contour N	[] umbers H	[] lands	
NAMING [
MEMORY Read list of words, so repeat them. Do 2 trials, even if 1st trial is successory to a recall after 5 minutes.		 	VET CHURCH	DAISY	RED	
ATTENTION Read list of digits (1	-	as to repeat them in the as to repeat them in the		[]218		
Read list of letters. The subject must tap with his hand at each letter A.						
Record number of errors [] FBACMNAAJKLBAFAKDEAAAJAMOFAAB Serial 7 subtraction starting at 100 [] 93 [] 86 [] 79 [] 72 [] 65						
4 or 5 correct subtractions: 3 pts , 2 or 3 correct: 2 pts , 1 correct: 1 pt , 0 correct: 0 pt LANGUAGE Repeat: I only know that John is the one to help today. [] The cat always hid under the couch when dogs were in the room. []						
	Fluency / Name maximum number of words in one minute that begin with the letter F. Record number of correct words []					
The cat a		egin with the letter F.	Record number of	correct words []	
The cat a Fluency / Name maximum number of		egin with the letter F.			J	
The cat a Fluency / Name maximum number of	words in one minute that be.g. banana - orange = fruit words	[] train – bio			1	

Administered by: _____

Alzheimer's Disea	ise Cooperative Stud

MoCA Fluency
Visit: EMCI Subjects Baseline
ADNI PARTICIPANT NUMBER

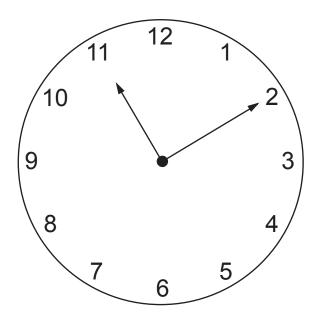
The examiner gives the following instruction:

"Tell me as many words as you can think of that begin with a certain letter of the alphabet that I will tell you in a moment. You can say any kind of word you want, except for proper nouns (like Bob or Boston), numbers, or words that begin with the same sound but have a different suffix, for example, love, lover, loving. I will tell you to stop after one minute. Are you ready? [Pause] Now, tell me as many words as you can think of that begin with the letter F. [time for 60 sec]. Stop.".

1	21	41
2	22	42
3	23	43
4	24	
5	25	45
6	26	46
7	27	47
8	28	48
9	29	49
10	30	50
11	31	51
12	32	52
13	33	53
14	34	54
15	35	55
16	36	56
17	37	57
18	38	58
19	39	59
20	40	60

Total Correct: _____

Alzheimer's Disease Cooperative Study								
Clock Drawing Test								
Visit: EMCI Subjects Baseline								
ADNI PARTICIPANT NUMBER EXAMINER INITIALS EXAMINATION DATE								
MONTH DAY YEAR								
1. Clock Drawing								
Instructions: Hand the subject a blank piece of paper and a pencil. Say to the subject: "Draw the face of a clock showing the numbers and the two hands, set to ten after eleven." If the subject is confused or asks for another try, allow the subject two attempts to complete the task. If a second attempt is done, ask the subject to indicate which one is better and score only that attempt. If requested, the examiner may remind the subject of the specific time to be shown on the clock face (see procedures manual for examples of correctly scored clock drawings).								
Scoring: CORRECT INCORRECT 1. Approximately circular face 2. Symmetry of number placement 3. Correctness of numbers 4. Presence of the two hands 5. Presence of the two hands, set to ten after eleven								
Total Correct (Range = 0-5) Count the number of CORRECT responses.								
Instructions: Immediately after the Clock drawing command condition is completed, present the subject with the response form with the model clock drawn at the top and say, "Copy this clock" (point to the model) "in the space provided below." Allow the subject to work without feedback; interrupt only if the subject starts to scratch out or destroy any of their drawing. If the subject tries to erase or scratch out an error, immediately intervene and gently instruct them to try again. Allow only two attempts on the Clock Copying test (see procedures manual for further instructions on scoring).								
Scoring: CORRECT INCORRECT 1. Approximately circular face 2. Symmetry of number placement 3. Correctness of numbers 4. Presence of the two hands 5. Presence of the two hands, set to ten after eleven Total Correct (Range = 0-5) Count the number of CORRECT responses.								



Alzheimer's Disease Cooperative Study



Category Fluency (Animals) Page 1 of 2 Visit: EMCI Subjects Baseline									
ADNI PARTICIPANT NUMBER	EXAMINER INITIALS EXAMINATION DATE MONTH DAY YEAR								
Task Instructions: Say, "I am going to give you a category and I want you to name, as fast as you can, all of the things that belong in that category. For example, if I say 'articles of clothing,' you could say, 'shirt', 'tie', or 'hat'. Can you think of other articles of clothing?" Allow up to 20 seconds for the subject to produce two responses. On the below table, check the responses and read the associated instruction.									
Response No response	"You could have said 'shoes' or 'coat' since they are articles of clothing."								
One or more incorrect responses, no correct response.	"No, is (are) not an article of clothing. You could have said 'shoes' or 'coat' since they are articles of clothing."								
One or more correct responses, no incorrect responses. "That's right. You could also have said 'shoes' or 'coat."									
One or more correct responses, one or more incorrect responses. " is (are) correct, but is (are) not an article of clothing. You also could have said 'shoes' or 'coat."									
☐ Two or more correct responses.	"That's right."								

PROCEED TO 'ANIMAL' CATEGORY WORK SHEETS

Alzheimer's Disease Cooperative Study



Visit:	EM	<u>CI S</u>	ubjec	ts E	<u>Basel</u>	ine

ADNI PARTICIPANT NUMBER							
		S	_				

Animal Category:

Say, "Now I want you to name things that belong to another category: Animals. You will have one minute. I want you to tell me all the animals you can think of in one minute. Ready? Begin."

- **○** Start timer as you say 'Begin'. Write actual responses as legibly as possible.
- ⇒ Stop the procedure at 60 seconds.

Perseverations:

Intrusions:

1	21	41
2	22	42
3	23	43
4	24	44
5	25	45
6	26	46
7	27	47
8	28	48
9	29	49
10	30	50
11	31	51
12	32	52
13	33	53
14	34	54
15	35	55
16	36	56
17	37	57
18	38	58
19	39	59
20	40	60

			Packet Version
Alzheimer's Disease Cooperati	ve Study		
	Tr	ail Making Tes	st
	Visi	it: EMCI Subjects Baselii	ne
ADNI PARTICIPA		EXAMINER INITIALS	EXAMINATION DATE
S			MONTH DAY YEAR
Part A Instructions: F	Place the Part A samp	ole form in front of the sub	eject. Read aloud the instructions.
number to number), th you move f If the subject makes ar say, for example, "You say, "Please start here	the next, in order. Seen go to three (poi from one circle to the error, mark through were at number two eand continue."	Start at 1 (point to the nument to the number) and some next. Work as quickly and the line and go back to the co. What is the next numbers, go to TEST A. Repeat to	the pencil and draw a line from one mber), then go to two (point to the on. Please try not to lift the pencil as as you can." the point at which the error was made and per?" Wait for the subject's response and the instructions given for the sample. Start
	when Trail is complet conds for the test.	ed or stop subject when n	naximum time is reached.
Scoring:	Part A time to comp	olete:	
Pa	art A errors of Comis	sion:	
I	Part A errors of Omis	sion:	
	ace the Part B samp	·	ject. Read aloud the instructions.

Say, "There are numbers and letters in circles on this page. Please take the pencil and draw a line, alternating in order between the numbers and letters. Start at number 1 (point to the number), then go to the first letter, A (point to the letter), then go to the next number, 2 (point to the number), and then the next letter, B (point to the letter), and so on. Please try not to lift the pencil as you move from one circle to the next. Work as quickly as you can."

If the subject makes an error, mark through the line and go back to the point at which the error was made and say, for example, "You were at number two. What is the next letter?" Wait for the subject's response and say, "Please start here and continue."

If the subject completes the sample correctly, go to **TEST B**. Repeat the instructions given for the sample. Start timing as soon as the instruction is given to begin.

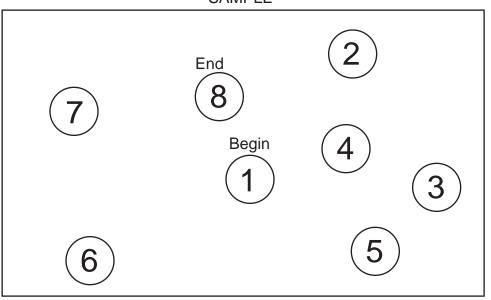
- Stop timing when Trail is completed or stop subject when maximum time is reached.
- Allow 300 seconds for the test.

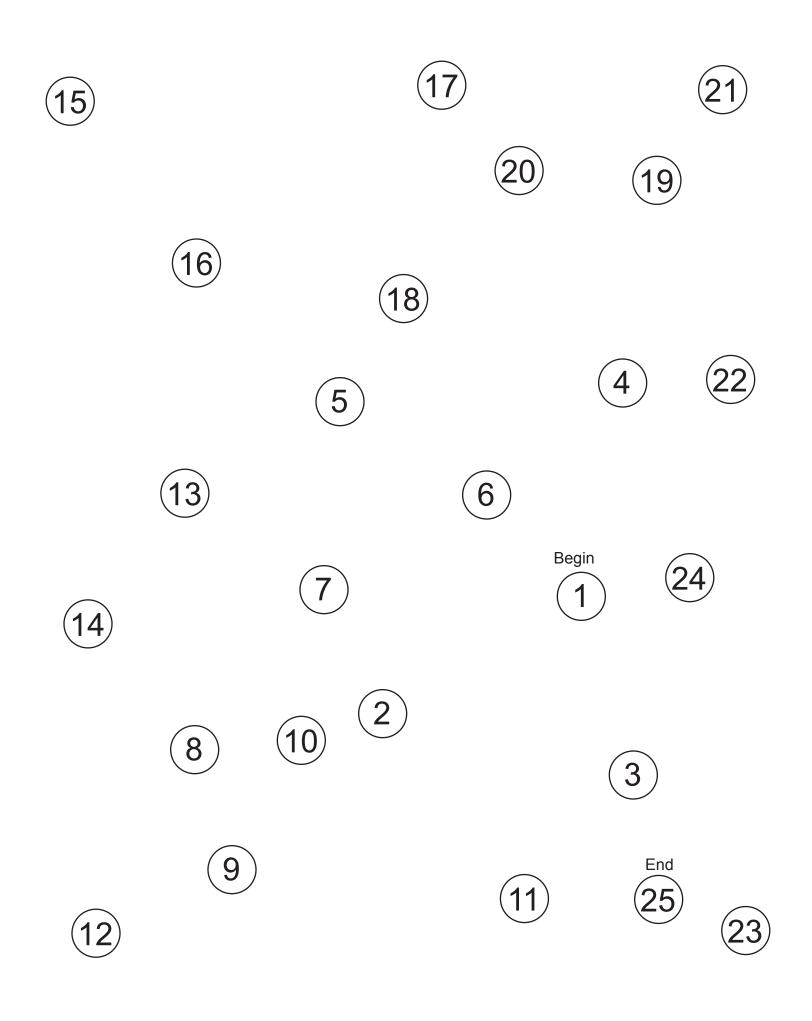
Scoring: Part B time to complete: _____ Part B errors of Comission: Part B errors of Omission: ____

TRAIL MAKING

PART A

SAMPLE

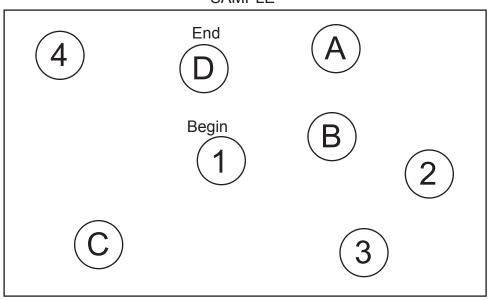




TRAIL MAKING

PART B

SAMPLE



End Begin 6

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e Study Auditory Verbal Learning Test (A.V.L.T.) Version A - 30 Minute Delay Visit: EMCI Subjects Baseline **EXAMINATION DATE EXAMINER INITIALS** ADNI PARTICIPANT NUMBER S MONTH YEAR DELAY: **30 Minute Delay Instructions:** (minutes) Say, "Awhile ago I read a list of words to you several times, and you had to repeat back the words. Tell me the words from that list." IMPORTANT: The words from the original list are <u>NOT</u> read again before recall is elicited on this trial **30 MINUTE** List A **DELAY** (DO NOT READ) **Drum Curtain** Bell Coffee School **Parent** Moon Garden Hat **Farmer** Nose **Turkey** Color House River **Totals Intrusions Recognition Instructions:** Say, "Sometimes people can remember more of the words if they see them. Read all these words and circle the ones that you think were on that first list I read...the list I read 5 times to you." LIST SCORES: Recognition: _____ Total Intrusions: ____

Teacher Coffee

River Road

Bridge Hat

Farmer Turkey

Pen Minute

Forehead Nose

Kerchief School

House Bell

Moon Face

Color Garden

Beet Classroom

Curtain Parent

Floor Children

Soldier Broomstick

Drum Gun

Alzheimer's Disease Cooperative Stud
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Everyday Cognition (ECog) - Participant Self-Report

Visit: EMCI Subjects Baseline							
ADNI PARTICIPANT NUMBER EXAMINER INITIALS EXAMINATION DATE							
MONTH DAY YEAR							
ADNI Administration procedures for the ECog:							
→ Participants and their study partners will each complete this questionnaire independently, within the clinic, at the time of their ADNI in-clinic visit.							
⇒ Research assistants will check all ECog forms before the end of the visit to ensure they are completed fully and, if necessary, direct the participant or study partner to complete the form.							
⇒ In some cases the participant may be too cognitively impaired to complete the form.							
☐ If the reading level of either the participant or the study partner is low, the research assistant may read the items out loud and record their ratings.							
◆ After the participant finishes the ECog, answer the following questions:							
1. How much assistance was needed from the research staff to complete this form?							
\square None \square A little \square A lot \square Participant too cognitively impaired to complete							
2. Validity of the information collected from the participant (based on research assistant's observations and interactions with the participant while they were completing the ECog):							
\square 1 = APPEARED VALID - The participant did not express any confusion or ask for any clarification in completing the ECog.							
\square 2 = QUESTIONABLE VALIDITY - The participant needed to have the instructions repeated, and/or needed help in understanding a few of the items.							
\square 3 = APPEARED INVALID - The participant was clearly confused about the content of many of the questions or how to complete the form in general).							
\Box 4 = NO INFORMATION COLLECTED FROM PARTICIPANT							

Participant Self Report Form

Page 1 of 3

DIRECTIONS: Please rate your ability to perform certain everyday tasks **NOW**, as compared to your ability to do these same tasks 10 years ago. In other words, try to remember how you were doing 10 years ago and indicate any change in your level of ability. Rate the amount of change on a five-point scale ranging from:

1	There has been no change in my ability or I actually perform better compared to 10 years ago.
2	I occasionally perform the task worse but not all of the time.
3	I consistently perform the task a little worse than 10 years ago.
4	I consistently perform the task much worse than 10 years ago.
9	I don't know.

Circle the number that fits your response.

Before we get started...

Are you concerned that you have a memory or other thinking problem? Yes No

Compared to 10 years ago, has there been any change in	BETTER OR NO CHANGE	QUESTIONABLE / OCCASIONALLY WORSE	CONSISTENTLY A LITTLE WORSE	CONSISTENTLY MUCH WORSE	I DON'T KNOW
MEMORY					
Remembering a few shopping items without a list.	1	2	3	4	9
Remembering things that happened recently (such as recent outings, events in the news).	1	2	3	4	9
3. Recalling conversations a few days later.	1	2	3	4	9
4. Remembering where I have placed objects.	1	2	3	4	9
5. Repeating stories and/or questions.	1	2	3	4	9
6. Remembering the current date or day of the week.	1	2	3	4	9
7. Remembering I have already told someone something.	1	2	3	4	9
8. Remembering appointments, meetings, or engagements.	1	2	3	4	9

Participant Self Report Form Page 2 of 3

Compared to 10 years ago, has there been any change in	BETTER OR NO CHANGE	QUESTIONABLE / OCCASIONALLY WORSE	CONSISTENTLY A LITTLE WORSE	CONSISTENTLY MUCH WORSE	I DON'T KNOW
LANGUAGE					
1. Forgetting the names of objects.	1	2	3	4	9
2. Verbally giving instructions to others.	1	2	3	4	9
3. Finding the right words to use in a conversation.	1	2	3	4	9
4. Communicating thoughts in a conversation.	1	2	3	4	9
5. Following a story in a book or on TV.	1	2	3	4	9
6. Understanding the point of what other people are trying to say.	1	2	3	4	9
7. Remembering the meaning of common words.	1	2	3	4	9
8. Describing a program I have watched on TV.	1	2	3	4	9
9. Understanding spoken directions or instructions.	1	2	3	4	9
VISUAL-SPATIAL AND PERCEPTUAL AB	ILITIES				
1. Following a map to find a new location.	1	2	3	4	9
Reading a map and helping with directions when someone else is driving.	1	2	3	4	9
3. Finding my car in a parking lot.	1	2	3	4	9
4. Finding my way back to a meeting spot in the mall or other location.	1	2	3	4	9
5. Finding my way around a familiar neighborhood.	1	2	3	4	9
6. Finding my way around a familiar store.	1	2	3	4	9
7. Finding my way around a house visited many times.	1	2	3	4	9

Participant Self Report Form Page 3 of 3

Compared to 10 years ago, has there been any change in	BETTER OR NO CHANGE	QUESTIONABLE / OCCASIONALLY WORSE	CONSISTENTLY A LITTLE WORSE	CONSISTENTLY MUCH WORSE	I DON'T KNOW
EXECUTIVE FUNCTIONING: PLANNING					
 Planning a sequence of stops on a shopping trip. 	1	2	3	4	9
2. The ability to anticipate weather changes and plan accordingly (i.e., bring a coat or umbrella.	1	2	3	4	9
3. Developing a schedule in advance of anticipated events.	1	2	3	4	9
4. Thinking things through before acting.	1	2	3	4	9
5. Thinking ahead.	1	2	3	4	9
EXECUTIVE FUNCTIONING: ORGANIZAT	TION				
 Keeping living and work space organized. 	1	2	3	4	9
Balancing the checkbook without error.	1	2	3	4	9
3. Keeping financial records organized.	1	2	3	4	9
4. Prioritizing tasks by importance.	1	2	3	4	9
5. Keeping mail and papers organized.	1	2	3	4	9
 Using an organized strategy to manage a medication schedule involving multiple medications. 	1	2	3	4	9
EXECUTIVE FUNCTIONING: DIVIDED AT	TTENTIO	N			
1. The ability to do two things at once.	1	2	3	4	9
2. Returning to a task after being interrupted.	1	2	3	4	9
3. The ability to concentrate on a task without being distracted by external things in the environment.	1	2	3	4	9
4. Cooking or working and talking at the same time.	1	2	3	4	9



Everyday Cognition (ECog) - Study Partner Report

,	Visit: EMCI Subjects Baselii	ne
ADNI PARTICIPANT NUMBER	EXAMINER INITIALS	EXAMINATION DATE
S-		MONTH DAY YEAR

ADNI Administration procedures for the ECog:

- → Participants and their study partners will each complete this questionnaire independently, within the clinic, at the time of their ADNI in-clinic visit.
- Research assistants will check all ECog forms before the end of the visit to ensure they are completed fully and, if necessary, direct the participant or study partner to complete the form.
- In some cases the participant may be too cognitively impaired to complete the form.
- ➡ If the reading level of either the participant or the study partner is low, the research assistant may read the items out loud and record their ratings.

Study Partner Report Form

Page 1 of 3

DIRECTIONS: Please rate the participant's ability to perform certain everyday tasks **NOW**, *as compared to his/her ability to do these same tasks 10 years ago.* In other words, try to remember how he/she was doing 10 years ago and indicate any change you have seen. Rate the amount of change on a five-point scale ranging from:

1	No change or actually performs better than 10 years ago.
2	Occasionally performs the task worse but not all of the time.
3	Consistently performs the task a little worse than 10 years ago.
4	Consistently performs the task much worse than 10 years ago.
9	I don't know.

Circle the number that fits your response.

Compared to 10 years ago, has there been any change in	BETTER OR NO CHANGE	QUESTIONABLE / OCCASIONALLY WORSE	CONSISTENTLY A LITTLE WORSE	CONSISTENTLY MUCH WORSE	I DON'T KNOW	
MEMORY						
Remembering a few shopping items without a list.	1	2	3	4	9	
Remembering things that happened recently (such as recent outings, events in the news).	1	2	3	4	9	
3. Recalling conversations a few days later.	1	2	3	4	9	
4. Remembering where he/she has placed objects.	1	2	3	4	9	
5. Repeating stories and/or questions.	1	2	3	4	9	
6. Remembering the current date or day of the week.	1	2	3	4	9	
7. Remembering he/she has already told someone something.	1	2	3	4	9	
8. Remembering appointments, meetings, or engagements.	1	2	3	4	9	

Study Partner Report Form Page 2 of 3

Compared to 10 years ago, has there been any change in	BETTER OR NO CHANGE	QUESTIONABLE / OCCASIONALLY WORSE	CONSISTENTLY A LITTLE WORSE	CONSISTENTLY MUCH WORSE	I DON'T KNOW
LANGUAGE					I
1. Forgetting the names of objects.	1	2	3	4	9
2. Verbally giving instructions to others.	1	2	3	4	9
3. Finding the right words to use in a conversation.	1	2	3	4	9
4. Communicating thoughts in a conversation.	1	2	3	4	9
5. Following a story in a book or on TV.	1	2	3	4	9
6. Understanding the point of what other people are trying to say.	1	2	3	4	9
7. Remembering the meaning of common words.	1	2	3	4	9
8. Describing a program he/she has watched on TV.	1	2	3	4	9
9. Understanding spoken directions or instructions.	1	2	3	4	9
VISUAL-SPATIAL AND PERCEPTUAL ABIL	LITIES				1
1. Following a map to find a new location.	1	2	3	4	9
Reading a map and helping with directions when someone else is driving.	1	2	3	4	9
3. Finding one's car in a parking lot.	1	2	3	4	9
4. Finding the way back to a meeting spot in the mall or other location.	1	2	3	4	9
Finding his/her way around a familiar neighborhood.	1	2	3	4	9
6. Finding his/her way around a familiar store.	1	2	3	4	9
7. Finding his/her way around a house visited many times.	1	2	3	4	9

Study Partner Report Form Page 3 of 3

Compared to 10 years ago, has there been any change in	BETTER OR NO CHANGE	QUESTIONABLE / OCCASIONALLY WORSE	CONSISTENTLY A LITTLE WORSE	CONSISTENTLY MUCH WORSE	I DON'T KNOW
EXECUTIVE FUNCTIONING: PLANNING					
Planning the sequence of stops on a shopping trip.	1	2	3	4	9
The ability to anticipate weather changes and plan accordingly (i.e., bring a coat or umbrella.	1	2	3	4	9
3. Developing a schedule in advance of anticipated events.	1	2	3	4	9
4. Thinking things through before acting.	1	2	3	4	9
5. Thinking ahead.	1	2	3	4	9
EXECUTIVE FUNCTIONING: ORGANIZAT	ION				
Keeping living and work space organized.	1	2	3	4	9
Balancing the checkbook without error.	1	2	3	4	9
3. Keeping financial records organized.	1	2	3	4	9
4. Prioritizing tasks by importance.	1	2	3	4	9
5. Keeping mail and papers organized.	1	2	3	4	9
 Using an organized strategy to manage a medication schedule involving multiple medications. 	1	2	3	4	9
EXECUTIVE FUNCTIONING: DIVIDED AT	TENTION				
1. The ability to do two things at once.	1	2	3	4	9
Returning to a task after being interrupted.	1	2	3	4	9
The ability to concentrate on a task without being distracted by external things in the environment.	1	2	3	4	9
4. Cooking or working and talking at the same time.	1	2	3	4	9