Alzheimer's Disease Neuroimaging Initiative
Grand Opportunity
ADNI GO

Worksheet Packet

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 ^{18}F-AV-45 Amyloid imaging will still be followed for cognitive and clinical assessments.

Alzheimer's Disease Cooperative Study

ADCS

Inclusion Criteria

Visit: EMCI Screening

ADNI PARTICIPANT NUMBER | | | | S | | | | |

EXAMINER INITIALS | | | |

EXAMINATION DATE | | | | | | | | | | |

MONTH DAY YEAR

Instructions: 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.
   - ☐ Yes
   - ☐ No

2. 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

3. 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

5. 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

Alzheimer's Disease Cooperative Study

ADCS

Inclusion Criteria

Visit: EMCI Screening

ADNI PARTICIPANT NUMBER

			S				

7. Geriatric Depression Scale less than 6.
   - ☐ Yes
   - ☐ No

8. Age between 55-90 (inclusive).
   - ☐ Yes
   - ☐ 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

Alzheimer's Disease Cooperative Study

ADCS

Inclusion Criteria

Visit: EMCI Screening

ADNI PARTICIPANT NUMBER

			S				

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

Alzheimer's Disease Cooperative Study

ADCS

Exclusion Criteria

Visit: EMCI Screening

ADNI PARTICIPANT NUMBER | | | | S | | | | |

EXAMINER INITIALS | | | |

EXAMINATION DATE | | | | | | | | | |
MONTH DAY YEAR

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.

1. 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

2. 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.
   - ☐ Yes
   - ☐ No

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).
   - ☐ Yes
   - ☐ No

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

Alzheimer's Disease Cooperative Study

ADCS

Exclusion Criteria

Visit: EMCI Screening

ADNI PARTICIPANT NUMBER

			S				

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).
   - ☐ Yes
   - ☐ No

11. Investigational agents are prohibited one month prior to entry and for the duration of the trial.
   - ☐ Yes
   - ☐ No

12. Participation in clinical studies involving neuropsychological measures being collected more than one time per year.
   - ☐ Yes
   - ☐ 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

Alzheimer's Disease Cooperative Study

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Geriatric Depression Scale

Visit: EMCI Screening

ADNI PARTICIPANT NUMBER ☐☐☐-S-☐☐☐☐

EXAMINER INITIALS ☐☐☐

EXAMINATION DATE ☐☐ MONTH ☐☐ DAY ☐☐☐☐ YEAR

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

☐ 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 Study

ADCS

Geriatric Depression Scale

Visit: EMCI Screening

ADNI PARTICIPANT NUMBER

			S				

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: _____

Alzheimer's Disease Cooperative Study

ADCS

Clinical Dementia Rating

ADNI PARTICIPANT NUMBER ☐☐☐-S-☐☐☐☐

EXAMINER INITIALS ☐☐☐

EXAMINATION DATE ☐☐ MONTH ☐☐ DAY ☐☐☐☐ YEAR

Scoring

See procedures manual for scoring instructions

Sum of Boxes ☐☐.☐

Global CDR ☐.☐

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 retained; 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 affairs 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 handling 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 independently at these activities though may still be engaged in some; appears normal to casual inspection	No pretense of independent function outside home: Appears well enough to be taken to functions outside a family home	No pretense of independent function outside home: Appears too ill 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 capable of self care		Needs prompting	Requires assistance in dressing, hygiene, keeping of personal effects	Requires much help with personal care; frequent incontinence

Alzheimer's Disease Cooperative Study

ADCS

Clinical Dementia Rating

Visit: EMCI Screening

ADNI PARTICIPANT NUMBER ___ ___ ___ – S – ___ ___ ___ ___

EXAMINER INITIALS ___ ___ ___

EXAMINATION DATE ___ ___ (MONTH) ___ ___ (DAY) ___ ___ ___ ___ (YEAR)

This is a semi-structured interview. Please ask all of these questions. Ask any additional questions necessary to determine the subject's CDR. Please record information from the additional questions.

Memory Questions for Study Partner:

1. Does he/she have a problem with his/her memory or thinking? ☐ Yes ☐ No
1a. If yes, is this a consistent problem (as opposed to inconsistent)? ☐ Yes ☐ No
2. Can he/she recall recent events? ☐ Usually ☐ Sometimes ☐ Rarely
3. Can he/she remember a short list of items (shopping)? ☐ Usually ☐ Sometimes ☐ Rarely
4. Has there been some decline in memory during the past year? ☐ 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 distant past (e.g., birth date, wedding date, place of employment)? ☐ Usually ☐ Sometimes ☐ Rarely
9. Tell me about some recent event in his/her life that he/she should remember. (For later testing, obtain details such as location of the event, time of day, participants, how long the event was, when it ended and 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 employed)? _____
14. What was his/her last major job (or spouse's job if subject was not employed)? _____
15. When did he/she (or spouse) retire and why? _____

Alzheimer's Disease Cooperative Study

ADCS

Clinical Dementia Rating

Visit: EMCI Screening

ADNI PARTICIPANT NUMBER

[ ][ ][ ]-S-[ ][ ][ ][ ]

Orientation Questions for Study Partner:

How often does he/she know of the exact:

1. Date of the 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 Week?
   ☐ Usually ☐ Sometimes ☐ Rarely ☐ Don't Know

5. Does he/she have difficulty with time relationships (when events happened in relation to each other)?
   ☐ Usually ☐ Sometimes ☐ Rarely ☐ Don't Know

6. Can he/she find his/her way about familiar streets?
   ☐ Usually ☐ Sometimes ☐ Rarely ☐ Don't Know

7. How often does he/she know how to get from one place to another outside his/her neighborhood?
   ☐ Usually ☐ Sometimes ☐ Rarely ☐ Don't Know

8. How often can he/she find his/her way about indoors?
   ☐ Usually ☐ Sometimes ☐ Rarely ☐ Don't Know

Alzheimer's Disease Cooperative Study

ADCS

Clinical Dementia Rating

Visit: EMCI Screening

ADNI PARTICIPANT NUMBER

			–	S	–			

Judgment and Problem Solving Questions for Study Partner:

1. 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):
   - ☐ 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

Alzheimer's Disease Cooperative Study

ADCS

Clinical Dementia Rating

Visit: EMCI Screening

ADNI PARTICIPANT NUMBER

[ ][ ][ ]-S-[ ][ ][ ][ ]

Community Affairs Questions for Study Partner:

Occupational

1. Is the subject still working? ☐ Yes ☐ No ☐ 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 to retire? (Question 4 is next) ☐ Yes ☐ No ☐ DK
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

Social

4. Did he/she ever drive a car? ☐ Yes ☐ No
   Does the subject drive a car now? ☐ Yes ☐ No
   If no, is this because of memory or thinking problems? ☐ Yes ☐ No
5. If he/she is still driving, are there problems or risks because of poor thinking? ☐ Yes ☐ No

*6. Is he/she able to independently shop for needs?
   ☐ Rarely or Never (Needs to be accompanied on any shopping trip)
   ☐ Sometimes (Shops for limited number of items; buys duplicate items or forgets needed items)
   ☐ Usually
   ☐ Don't Know

7. Is he/she able to independently carry out activities outside the home?
   ☐ Rarely or Never (Generally unable to perform activities without help)
   ☐ Sometimes (Limited and/or routine, e.g., superficial participation in church or meetings; trips to beauty parlor)
   ☐ Usually (Meaningful participation in activities, e.g., voting.)
   ☐ Don't Know
8. Is he/she taken to social functions outside a family home? ☐ Yes ☐ No

   If no, why not? _____
9. Would a casual observer of the subject's behavior think the subject was ill? ☐ Yes ☐ No
10. If in nursing home, does he/she participate well in social functions (thinking)? ☐ Yes ☐ No

IMPORTANT:
Is there enough information to rate the subject's level of impairment in community affairs?
If not, please probe further.

Community Affairs: Such as going to church, visiting friends and family, political activities, professional organizations such as bar association, other professional groups, social clubs, service organizations, educational programs.

*Please add notes if needed to clarify subject's level of functioning in this area.

Alzheimer's Disease Cooperative Study

ADCS

Clinical Dementia Rating

Visit: EMCI Screening

ADNI PARTICIPANT NUMBER

				S				

Home 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):

	No Loss		Severe Loss
4. Ability to perform household tasks	0	0.5	1

Please describe: _____

_____

_____

5. 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.
(Operates appliances, such as a vacuum cleaner; prepares simple meals)
- ☐ Functions in usual activities but not at usual level.
- ☐ Normal function in usual 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.

Alzheimer's Disease Cooperative Study

ADCS

Clinical Dementia Rating

Visit: EMCI Screening

ADNI PARTICIPANT NUMBER

			S				

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.

Alzheimer's Disease Cooperative Study

ADCS

Clinical Dementia Rating

Visit: EMCI Screening

ADNI PARTICIPANT NUMBER

				S				

Memory Questions for Subject:

1. Do you have problems with memory or thinking? ☐ Yes ☐ No
2. A few moments ago, your (spouse, etc.) told me a few recent experiences you had. Will you tell me some thing about those? (Prompt for details, if needed, such as location of the event, time of day, participants, how long the event was, when it ended and how the subject or other participants got there.)

Within 1 week

1.0 - Largely correct _____

0.5 _____

0.0 - Largely incorrect _____

Within 1 month

1.0 - Largely correct _____

0.5 _____

0.0 - Largely incorrect _____

3. I will give you a name and address to remember for a few minutes. Repeat this name and address after me: (Repeat until the phrase is correctly repeated or to a maximum of three trials.)

Elements	1	2	3	4	5
	John	Brown,	42	Market Street,	Chicago
	John	Brown,	42	Market Street,	Chicago
	John	Brown,	42	Market Street,	Chicago

(Underline elements repeated correctly in each trial)

4. When were you born? _____
5. Where were you born? _____
6. What was the last school you attended? _____

   Name _____

   Place _____ Grade _____
7. What was your main occupation/job (or spouse if not employed)? _____
8. What was your last major job (or spouse if not employed)? _____
9. When did you (or spouse) retire and why? _____
10. Repeat the name and address I asked you to remember:

Elements	1	2	3	4	5
	John	Brown,	42	Market Street,	Chicago

☐ None correctly Repeated

(Underline elements repeated correctly in each trial.)

Alzheimer's Disease Cooperative Study

ADCS

Clinical Dementia Rating

Visit: EMCI Screening

ADNI PARTICIPANT NUMBER

				S				

Orientation Questions for Subject:

Record 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 Study

ADCS

Clinical Dementia Rating

Visit: EMCI Screening

ADNI PARTICIPANT NUMBER

[ ][ ][ ] S [ ][ ][ ][ ]

Judgment and Problem Solving Questions for Subject:

Instructions: If initial response by subject does not merit a score of 0, press the matter to identify the subject's best understanding of the problem. Circle nearest response.

Similarities:

Example: "How are a pencil and pen alike?" (writing instruments)

"How are these things alike?" Subject's response

1. turnip.....cauliflower _____
   (0 = vegetables)
   (1 = edible foods, living things, can be cooked, etc.)
   (2 = answers not pertinent; differences; buy item)

2. desk.....bookcase _____
   (0 = furniture, office furniture, both hold books)
   (1 = wooden, legs)
   (2 = not pertinent; differences; buy item)

Differences:

Example: "What is the difference between sugar and vinegar?" (sweet vs. sour)

"What is the difference between these things?" Subject's response

3. lie.....mistake _____
   (0 = one deliberate, one unintentional)
   (1 = one bad the other good - or explains only one)
   (2 = anything else, similarities)

4. river.....canal _____
   (0 = natural - artificial)
   (2 = anything else)

Calculations: Subject's response

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 locate a friend that you wished to see?
   0 = try the telephone book, city directory, go to the courthouse for a directory; call a mutual friend
   1 = call the police, call operator (usually will not give address)
   2 = no clear response

9. Subject's assessment of disability and station in life and understanding of why he/she is present at the examination (may have covered, but rate here):

   ☐ Good Insight ☐ Partial Insight ☐ Little Insight

Alzheimer's Disease Cooperative Study

ADCS

Clinical Dementia Rating

Visit: EMCI Screening

ADNI PARTICIPANT NUMBER

				S				

Notes, Comments, Summary Statement

Alzheimer's Disease Cooperative Study

ADCS

Neuropsychiatric Inventory Q

Visit: EMCI Subjects Baseline

ADNI PARTICIPANT NUMBER | | | | S | | | | |

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).

Alzheimer's Disease Cooperative Study

ADCS

Neuropsychiatric Inventory Q

Visit: EMCI Subjects Baseline

ADNI PARTICIPANT NUMBER

				S				

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).

Alzheimer's Disease Cooperative Study

ADCS

Neuropsychiatric Inventory Q

Visit: EMCI Subjects Baseline

ADNI PARTICIPANT NUMBER

				S				

I. IRRITABILITY/LABILITY *Is {P} impatient or cranky? Does he/she have difficulty coping with delays or waiting 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).

J. ABERRANT MOTOR BEHAVIOR *Does {P} engage in repetitive activities, such as pacing around the house, handling 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).

K. SLEEP *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).

L. APPETITE AND EATING DISORDERS *Has {P} lost or gained weight, or had a change in the food he/she likes?*

- ☐ 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).

Total Score ☐

Alzheimer's Disease Cooperative Study

ADCS

Functional Assessment Questionnaire

Visit: EMCI Subjects Baseline

ADNI PARTICIPANT NUMBER ☐☐☐-S-☐☐☐☐ 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)

Alzheimer's Disease Cooperative Study

ADCS

Functional Assessment Questionnaire

Visit: EMCI Subjects Baseline

ADNI PARTICIPANT NUMBER

			S				

6. Preparing a balanced meal.

- ☐ 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)

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)

Total Score ☐

Alzheimer's Disease Cooperative Study

ADCS

Vital Signs

Visit: EMCI Screening

ADNI PARTICIPANT NUMBER ___ ___ ___ – S – ___ ___ ___ ___

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:

_____

_____

_____

Alzheimer's Disease Cooperative Study

ADCS

Physical Exam

Visit: EMCI Screening

ADNI PARTICIPANT NUMBER ☐☐☐-S-☐☐☐☐

EXAMINER INITIALS ☐☐☐

EXAMINATION DATE ☐☐ MONTH ☐☐ DAY ☐☐☐☐ YEAR

	NORMAL	ABNORMAL	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 credentials:

☐ M.D. ☐ P.A. ☐ D.O. ☐ N.P. ☐ Other (specify) _____

16. Based on the Physical Examination, clinician must check appropriate box below:

☐ Findings consistent with eligibility for study

☐ Participant is not eligible for study

17. **Clinician's signature (required)** _____ **Date** _____

Alzheimer's Disease Cooperative Study

ADCS

Neurological Exam

Visit: EMCI Screening

ADNI PARTICIPANT NUMBER ☐☐☐-S-☐☐☐☐ EXAMINER INITIALS ☐☐☐ EXAMINATION DATE ☐☐ MONTH ☐☐ DAY ☐☐☐☐ YEAR

	Absent	Present	If "present", must provide details
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	☐	☐	Specify: _____

13. General comments _____

14. Confirm clinician's qualifying credentials:

☐ M.D. ☐ P.A. ☐ D.O. ☐ N.P. ☐ Other (specify) _____

15. Based on the Neurological Examination, clinician must check appropriate box below:

☐ Findings consistent with eligibility for study ☐ Participant is not eligible for study

16. **Clinician's Signature (required)** _____ **Date** _____

Alzheimer's Disease Cooperative Study

ADCS

Participant Demographics

Visit: EMCI Screening

ADNI PARTICIPANT NUMBER ☐☐☐-S-☐☐☐☐

EXAMINER INITIALS ☐☐☐

EXAMINATION DATE ☐☐ 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: ☐☐ MONTH ☐☐ DAY ☐☐☐☐ YEAR

Alzheimer's Disease Cooperative Study

ADCS

Participant Demographics

Visit: EMCI Screening

ADNI PARTICIPANT NUMBER

[ ][ ][ ]-S-[ ][ ][ ][ ]

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):

[ ][ ][ ][ ]

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

Alzheimer's Disease Cooperative Study

ADCS

Family History Questionnaire

Visit: EMCI Screening

ADNI PARTICIPANT NUMBER | | | | S | | | | |

EXAMINER INITIALS | | | |

EXAMINATION DATE | | | | | | | | | |
MONTH DAY YEAR

Instructions: 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.

NOTE: Alzheimer's Disease should only be answered when Dementia is answered "Yes."

Information Souce

- ☐ Participant Visit
- ☐ Telephone Call

Indicate below who provided the information collected for this questionnaire:

- ☐ Participant only
- ☐ Study Partner only
- ☐ Both Participant and Study Partner

1. Mother

   Dementia
   - ☐ Yes
   - ☐ No
   - ☐ Don't Know

   Alzheimer's Disease
   - ☐ Yes
   - ☐ No
   - ☐ Don't Know

2. Father

   Dementia
   - ☐ Yes
   - ☐ No
   - ☐ Don't Know

   Alzheimer's Disease
   - ☐ Yes
   - ☐ No
   - ☐ Don't Know

Alzheimer's Disease Cooperative Study

ADCS

Family History Questionnaire

Visit: EMCI Screening

ADNI PARTICIPANT NUMBER

[ ][ ][ ]-S-[ ][ ][ ][ ]

3. Does the participant have any siblings? *(If yes, please provides additional information below.)*
   - ☐ Yes
   - ☐ No

   Details: _____

Sibling 1:	Gender:	☐ Male ☐ Female	Dementia:	☐ Yes ☐ No ☐ Don't Know	Alzheimer's Disease:	☐ Yes ☐ No ☐ Don't Know
Sibling 2:	Gender:	☐ Male ☐ Female	Dementia:	☐ Yes ☐ No ☐ Don't Know	Alzheimer's Disease:	☐ Yes ☐ No ☐ Don't Know
Sibling 3:	Gender:	☐ Male ☐ Female	Dementia:	☐ Yes ☐ No ☐ Don't Know	Alzheimer's Disease:	☐ Yes ☐ No ☐ Don't Know
Sibling 4:	Gender:	☐ Male ☐ Female	Dementia:	☐ Yes ☐ No ☐ Don't Know	Alzheimer's Disease:	☐ Yes ☐ No ☐ Don't Know
Sibling 5:	Gender:	☐ Male ☐ Female	Dementia:	☐ Yes ☐ No ☐ Don't Know	Alzheimer's Disease:	☐ Yes ☐ No ☐ Don't Know
Sibling 6:	Gender:	☐ Male ☐ Female	Dementia:	☐ Yes ☐ No ☐ Don't Know	Alzheimer's Disease:	☐ Yes ☐ No ☐ Don't Know
Sibling 7:	Gender:	☐ Male ☐ Female	Dementia:	☐ Yes ☐ No ☐ Don't Know	Alzheimer's Disease:	☐ Yes ☐ No ☐ Don't Know
Sibling 8:	Gender:	☐ Male ☐ Female	Dementia:	☐ Yes ☐ No ☐ Don't Know	Alzheimer's Disease:	☐ Yes ☐ No ☐ Don't Know
Sibling 9:	Gender:	☐ Male ☐ Female	Dementia:	☐ Yes ☐ No ☐ Don't Know	Alzheimer's Disease:	☐ Yes ☐ No ☐ Don't Know

Alzheimer's Disease Cooperative Study

ADCS

Medical History

Visit: EMCI Screening

ADNI PARTICIPANT NUMBER ☐☐☐-S-☐☐☐☐

EXAMINER INITIALS ☐☐☐

EXAMINATION DATE ☐☐ 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.

Information Source: ☐ Participant Visit ☐ Telephone Call

REVIEW OF SYSTEMS	YES	NO
1. Psychiatric	☐	☐
2. Neurologic	☐	☐
3. Head, Eyes, Ears, Nose, Throat	☐	☐
4. Cardiovascular	☐	☐
5. Respiratory	☐	☐
6. Hepatic	☐	☐
7. Dermatologic-Connective Tissue	☐	☐
8. Musculoskeletal	☐	☐
9. Endocrine-Metabolic	☐	☐
10. Gastrointestinal	☐	☐
11. Hematopoietic-Lymphatic	☐	☐
12. Renal-Genitourinary	☐	☐
13. Allergies or Drug Sensitivities	☐	☐

	YES	NO
14. Alcohol Abuse	☐	☐

If Yes to Alcohol Abuse:

14a. During period of alcohol abuse, estimate the average number of drinks per day: _____

14b. Duration of abuse (years): _____

14c. Period of time since end of abuse (years): _____

15. Drug Abuse	☐	☐
16. Smoking	☐	☐

If Yes to Smoking:

16a. During periods of smoking, the average number of packs/day: _____

16b. Duration (years): _____

16c. If no longer smoking, provide period of time since stopped smoking (years): _____

17. Malignancy	☐	☐
18. Major Surgical Procedures	☐	☐
19. Other	☐	☐

20. General Comments: _____

_____

Alzheimer's Disease Cooperative Study
ADCS

Medical History - Supplemental Form

page ____ of ____
Visit: EMCI Screening

ADNI PARTICIPANT NUMBER [ ][ ][ ] - S - [ ][ ][ ][ ]

EXAMINER INITIALS [ ][ ][ ]

EXAMINATION DATE [ ][ ] [ ][ ] [ ][ ][ ][ ]
MONTH DAY YEAR

INSTRUCTIONS: Use this form if the participant has indicated a condition or problem in a system on the Medical History form. **Only list ONE condition/problem per line** and provide details for each, including the best estimate of date of onset. If Current condition, indicate whether the problem is **Stable**. If the participant is currently taking medication for a condition, the condition should be recorded below as **Current.** Actual medication should be recorded 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 ☐ No	☐ Yes ☐ No	☐ Medication ☐ Other ________

Alzheimer's Disease Cooperative Study

ADCS

Modified Hachinski

Visit: EMCI Screening

ADNI PARTICIPANT NUMBER | | | | S | | | | |

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".

☐

Alzheimer's Disease Cooperative Study

ADCS

Key Background Medications Form

Visit: EMCI Screening

ADNI PARTICIPANT NUMBER | | | | S | | | | |

EXAMINER INITIALS | | | |

EXAMINATION DATE | | | | | | | | | |
MONTH DAY YEAR

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
ADCS

Concurrent Medications

page ____ of ____

Check box corresponding to visit of last review/update for EMCI Participants:

☐ SC ☐ BL ☐ M 6 ☐ M 12 ☐ M 18

ADNI PARTICIPANT NUMBER: ☐☐☐ – S – ☐☐☐☐

EXAMINER INITIALS: ☐☐☐

EXAMINATION DATE: ☐☐ ☐☐ ☐☐☐☐
MONTH DAY YEAR

Instructions: 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	Reason Prescribed	Continuing at Final Follow Up?
____________	__ / __ / __	☐☐ ☐☐ ☐☐☐☐	☐☐ ☐☐ ☐☐☐☐	☐ Adverse Event ☐ Therapeutic Use ☐ Prophylaxis/Non-therapeutic Use	☐
Reason Prescribed Details*: ____________					
____________	__ / __ / __	☐☐ ☐☐ ☐☐☐☐	☐☐ ☐☐ ☐☐☐☐	☐ Adverse Event ☐ Therapeutic Use ☐ Prophylaxis/Non-therapeutic Use	☐
Reason Prescribed Details*: ____________					
____________	__ / __ / __	☐☐ ☐☐ ☐☐☐☐	☐☐ ☐☐ ☐☐☐☐	☐ Adverse Event ☐ Therapeutic Use ☐ Prophylaxis/Non-therapeutic Use	☐
Reason Prescribed Details*: ____________					
____________	__ / __ / __	☐☐ ☐☐ ☐☐☐☐	☐☐ ☐☐ ☐☐☐☐	☐ 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 clarification
* 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.

Alzheimer's Disease Cooperative Study

ADCS

Diagnostic Summary

Baseline Changes Form

Visit: EMCI Month 6

ADNI PARTICIPANT NUMBER | | | | S | | | | |

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 indicate whether a conversion has occurred. Please use the narrative summary field to provide any other information used to support the diagnosis.

Physician's Initials: | | | |

Form Completed: | | | | | | | | | | |
MONTH DAY YEAR

Pre-visit Diagnosis:

☐ NL ☐ MCI ☐ AD

1. Clinically relevant worsening on ADAS?
   ☐ Yes ☐ No

2. Clinically relevant worsening on MMSE?
   ☐ Yes ☐ No

3. Clinically relevant worsening on MMSE recall?
   ☐ Yes ☐ No

4. Clinically relevant worsening on non-memory MMSE items?
   ☐ Yes ☐ No

5. Clinically relevant worsening in memory on neuropsych testing?
   ☐ Yes ☐ No

6. Clinically relevant impairment/worsening in non-memory cognitive domains on neuropsych testing?
   ☐ Yes ☐ No

7. Clinically relevant worsening in activities of daily living (FAQ)?
   ☐ Yes ☐ No

8. Clinically relevant deterioration on CDR Sum of Boxes or Overall CDR rating?
   ☐ Yes ☐ No

9. Clinically relevant depression based on clinical judgement or GDS?
   ☐ Yes ☐ No

Alzheimer's Disease Cooperative Study

ADCS

Diagnostic Summary

Baseline Changes Form

Visit: EMCI Month 6

ADNI PARTICIPANT NUMBER

			S				

10. Did subject have a stroke?
☐ Yes ☐ No

11. Is there evidence of a delirium (medication effect, toxic or metabolic encephalopathy)?
☐ Yes ☐ No

12. Has extenuating circumstance (such as a physical health problem, change in residence, charge in support network, death of a family member, etc.) contributed to a change in the subject's cognitive or functional performance?
☐ Yes ☐ No

If yes, describe: _____

_____

_____

_____

13. Is the change in clinical status corroborated by informant report of changes in ADL?
☐ Yes ☐ No ☐ NA/No change in clinical status

14. Is the change in clinical status corroborated by informant report of changes in cognition?
☐ Yes ☐ No ☐ NA/No change in clinical status

15. Narrative Summary: _____

_____

_____

_____

_____

_____

_____

Alzheimer's Disease Cooperative Study

ADCS

Diagnostic Summary

Visit: EMCI Month 6

ADNI PARTICIPANT NUMBER ☐☐☐-S-☐☐☐☐

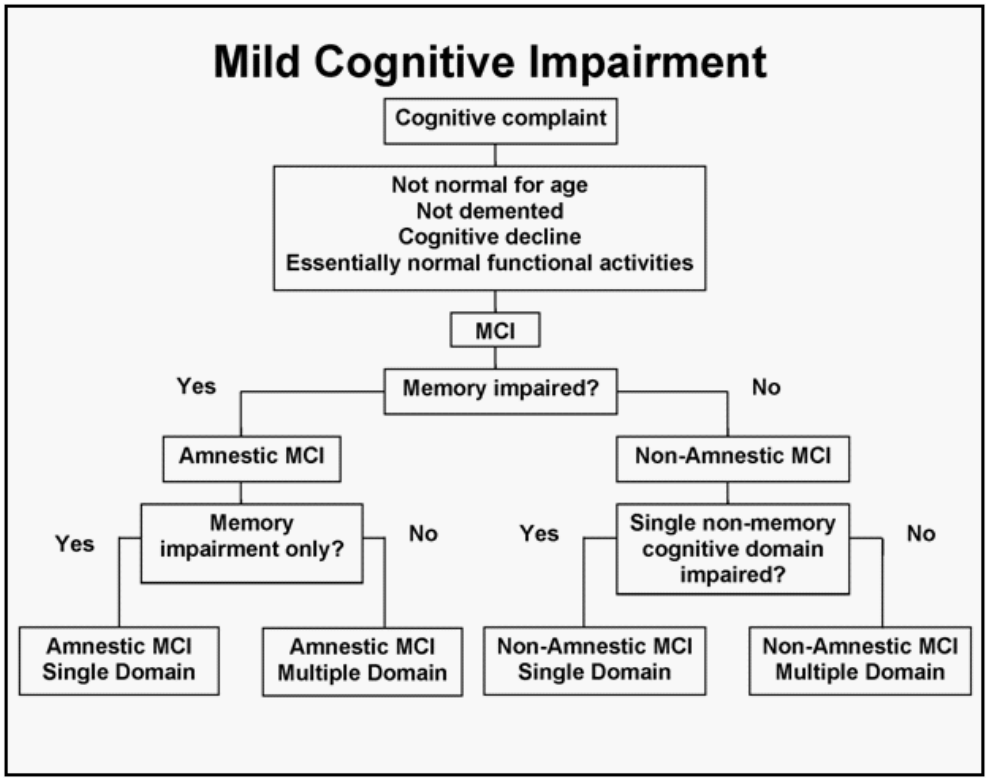
EXAMINER INITIALS ☐☐☐

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 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
- ☐ Stable: MCI to MCI
- ☐ Stable: Dementia to Dementia
- ☐ Conversion: NL to MCI
- ☐ Conversion: MCI to Dementia
- ☐ Conversion: NL to Dementia
- ☐ Reversion: MCI to NL
- ☐ Reversion: Dementia to MCI
- ☐ Reversion: Dementia to NL

Alzheimer's Disease Cooperative Study

ADCS

Diagnostic Summary

Visit: EMCI Month 6

ADNI PARTICIPANT NUMBER

			–	S	–				

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
- ☐ Yes
- ☐ 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): _____

Alzheimer's Disease Cooperative Study

ADCS

Diagnostic Summary

Visit: EMCI Month 6

ADNI PARTICIPANT NUMBER

			–	S	–				

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): _____

Alzheimer's Disease Cooperative Study

ADCS

Diagnostic Summary

Visit: EMCI Month 6

ADNI PARTICIPANT NUMBER

[ ][ ][ ]-[S]-[ ][ ][ ][ ]

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.

Alzheimer's Disease Cooperative Study

ADCS

Diagnosis and Symptoms Checklist

Visit: EMCI Month 6

ADNI PARTICIPANT NUMBER ☐☐☐-S-☐☐☐☐

EXAMINER INITIALS ☐☐☐

EXAMINATION DATE ☐☐ 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	Present
1. Nausea	☐	☐
2. Vomiting	☐	☐
3. Diarrhea	☐	☐
4. Constipation	☐	☐
5. Abdominal discomfort	☐	☐
6. Sweating	☐	☐
7. Dizziness	☐	☐
8. Low energy	☐	☐
9. Drowsiness	☐	☐
10. Blurred Vision	☐	☐
11. Headache	☐	☐
12. Dry Mouth	☐	☐
13. Shortness of Breath	☐	☐
14. Coughing	☐	☐
15. Palpitations	☐	☐
16. Chest pain	☐	☐
17. Urinary Discomfort (e.g., burning)	☐	☐

Symptom	Absent	Present
18. Urinary frequency	☐	☐
19. Ankle Swelling	☐	☐
20. Musculoskeletal	☐	☐
21. Rash	☐	☐
22. Insomnia	☐	☐
23. Depressed Mood	☐	☐
24. Crying	☐	☐
25. Elevated Mood	☐	☐
26. Wandering	☐	☐
27. Fall	☐	☐
28. Other Symptoms	☐	☐

Comments: _____

_____

_____

_____

Alzheimer's Disease Cooperative Study

ADCS

Baseline Symptoms Checklist

Visit: EMCI Screening

ADNI PARTICIPANT NUMBER [ ][ ][ ] S [ ][ ][ ][ ]

EXAMINER INITIALS [ ][ ][ ]

EXAMINATION DATE [ ][ ] MONTH [ ][ ] DAY [ ][ ][ ][ ] YEAR

Instructions: The Baseline Symptoms Checklist is completed at screening. Any condition or symptom present must be entered in the Baseline Symptoms Log which is then reviewed and updated at every visit. Complete this with information from both the participant and study partner. Episodic symptoms associated with medical conditions listed on the Medical History form should also be recorded on this form if they have occurred during the three months prior to the screening visit. If a diagnosis has been made, the diagnosis should be documented under "Other". Do not check symptoms associated with the diagnosis.

Symptom	Absent	Present
1. Nausea	☐	☐
2. Vomiting	☐	☐
3. Diarrhea	☐	☐
4. Constipation	☐	☐
5. Abdominal discomfort	☐	☐
6. Sweating	☐	☐
7. Dizziness	☐	☐
8. Low energy	☐	☐
9. Drowsiness	☐	☐
10. Blurred Vision	☐	☐
11. Headache	☐	☐
12. Dry Mouth	☐	☐
13. Shortness of Breath	☐	☐
14. Coughing	☐	☐
15. Palpitations	☐	☐
16. Chest pain	☐	☐
17. Urinary Discomfort (e.g., burning)	☐	☐

Symptom	Absent	Present
18. Urinary frequency	☐	☐
19. Ankle Swelling	☐	☐
20. Musculoskeletal	☐	☐
21. Rash	☐	☐
22. Insomnia	☐	☐
23. Depressed Mood	☐	☐
24. Crying	☐	☐
25. Elevated Mood	☐	☐
26. Wandering	☐	☐
27. Fall	☐	☐
28. Other Symptoms	☐	☐

Comments: _____

_____

_____

_____

Version 6

Alzheimer's Disease Cooperative Study

ADCS

Baseline Symptoms Log

page ______ of ______

Check box corresponding to visit of last review/update for EMCI Participants:

SC	BL	M 6	M 12	M 18
☐	☐	☐	☐	☐

ADNI PARTICIPANT NUMBER	EXAMINER INITIALS	EXAMINATION DATE
☐☐☐ - S - ☐☐☐☐	☐☐☐	☐☐ MONTH ☐☐ DAY ☐☐☐☐ YEAR

Instructions: 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 at Screening Visit**

SYMPTOM NUMBER	DESCRIPTION	SEVERITY	CHRONICITY	DATE OF ONSET	DATE CEASED	CONT'G AT FINAL FOLLOW UP?
☐☐		1 ☐ Mild 2 ☐ Moderate 3 ☐ Severe	1 ☐ Single occurrence 2 ☐ Intermittent 3 ☐ Persistent	☐☐ Month ☐☐ Day ☐☐☐☐ Year	☐☐ Month ☐☐ Day ☐☐☐☐ Year	☐
☐☐		1 ☐ Mild 2 ☐ Moderate 3 ☐ Severe	1 ☐ Single occurrence 2 ☐ Intermittent 3 ☐ Persistent	☐☐ Month ☐☐ Day ☐☐☐☐ Year	☐☐ Month ☐☐ Day ☐☐☐☐ Year	☐
☐☐		1 ☐ Mild 2 ☐ Moderate 3 ☐ Severe	1 ☐ Single occurrence 2 ☐ Intermittent 3 ☐ Persistent	☐☐ Month ☐☐ Day ☐☐☐☐ Year	☐☐ Month ☐☐ Day ☐☐☐☐ Year	☐
☐☐		1 ☐ Mild 2 ☐ Moderate 3 ☐ Severe	1 ☐ Single occurrence 2 ☐ Intermittent 3 ☐ Persistent	☐☐ Month ☐☐ Day ☐☐☐☐ Year	☐☐ Month ☐☐ Day ☐☐☐☐ Year	☐
☐☐		1 ☐ Mild 2 ☐ Moderate 3 ☐ Severe	1 ☐ Single occurrence 2 ☐ Intermittent 3 ☐ Persistent	☐☐ Month ☐☐ Day ☐☐☐☐ Year	☐☐ Month ☐☐ Day ☐☐☐☐ Year	☐

General Comments: ____

____

____

Alzheimer's Disease Cooperative Study

ADCS

Sample Collection: Clinical Labs

Visit: EMCI Screening

ADNI PARTICIPANT NUMBER ___ S ____

EXAMINER INITIALS ___

EXAMINATION DATE ___ (MONTH) ___ (DAY) ____ (YEAR)

ADNI GO PARTICIPANT

Instructions: Refer to the Procedures Manual for detailed instructions.

Test Review Date:

__ (MONTH) __ (DAY) ____ (YEAR)

1. Was blood drawn for safety labs?
   - ☐ Yes
   - ☐ No

   If No, explain: _____

2. Was a urine sample obtained for safety labs?
   - ☐ Yes
   - ☐ No

   If No, explain: _____

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.*
   - ☐ Yes
   - ☐ No

Clinician's Signature: _____ Date: _____

Alzheimer's Disease Cooperative Study

ADCS

Sample Collection: Biomarker Samples

Visit: EMCI Subjects Baseline

ADNI PARTICIPANT NUMBER ☐☐☐-S-☐☐☐☐

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:

1. Biomarker plain red-top tubes (2 blood collection tubes)
2. Biomarker lavender-top (2 blood collection tubes)
3. 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? ☐ Yes ☐ No

If yes, Date of Collection: ☐☐ 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: ☐ Sprotte ☐ Sharp

Method of Collection: ☐ Gravity ☐ Syringe suction

Overnight fast from midnight? ☐ Yes ☐ No

The exact date and time entered below must be noted on the specimen labels.

Date of Collection ☐☐ MONTH ☐☐ DAY ☐☐☐☐ YEAR

Time of Collection ☐☐ : ☐☐

Phlebotomist Initials: ☐☐☐

CSF Collector Initials: ☐☐☐

Alzheimer's Disease Cooperative Study

ADCS

Sample Collection: Biomarker Samples

Visit: EMCI Subjects Baseline

ADNI PARTICIPANT NUMBER

[ ][ ][ ] S [ ][ ][ ][ ]

2 Tubes of 10 ml PLAIN RED-TOP: Serum Samples

Time Collected [ ][ ] : [ ][ ] HH : MM

Amount Collected [ ] mL

Centrifuged Time [ ][ ] : [ ][ ] HH : MM

Transfer Time [ ][ ] : [ ][ ] HH : MM

Volume of Serum Transferred [ ] mL

Time Frozen [ ][ ] : [ ][ ] HH : MM

2 Tubes of 10 ml LAVENDER-TOP: Plasma Samples

Time Collected [ ][ ] : [ ][ ] HH : MM

Amount Collected [ ] mL

Centrifuged Time [ ][ ] : [ ][ ] HH : MM

Transfer Time [ ][ ] : [ ][ ] HH : MM

Volume of Plasma Transferred [ ] mL

Time Frozen [ ][ ] : [ ][ ] HH : MM

CSF

Time Collected [ ][ ] : [ ][ ] HH : MM

Amount Collected [ ] mL

Transfer Time [ ][ ] : [ ][ ] HH : MM

Volume of CSF Transferred [ ] mL

Time Frozen [ ][ ] : [ ][ ] HH : MM

Check if any of the following was performed:

- ☐ Lumbar Puncture Blood Patch
- ☐ Fluroscopy
- ☐ Lumbar Spine Film

Date of Blood Patch:

[ ][ ] MONTH [ ][ ] DAY [ ][ ][ ][ ] YEAR

If a Spine Film or Fluroscopy procedures was performed please complete the protocol deviation form and select item #14.

Date of Fluoroscopy

[ ][ ] Month [ ][ ] Day [ ][ ][ ][ ] Year

If Fluoroscopy performed, but no CSF was collected, provide explanation

_____

_____

_____

Alzheimer's Disease Cooperative Study

ADCS

Sample Collection: Biomarker Samples

Visit: EMCI Subjects Baseline

ADNI PARTICIPANT NUMBER

				S				

Date of Spine Film

MONTH DAY YEAR

If Spine Film performed, but no CSF was collected, provide explanation:

_____

_____

_____

FedEx Tracking Number: _____

Date FedExed

MONTH DAY YEAR

Please review the following chart regarding the license plate numbers to confirm that the appropriate label was used for the visit that was conducted:

Baseline	VST 2	200000 – 299999
Month 6	VST 3	300000 – 399999
Month 12	VST 4	400000 – 499999
Month 24	VST 6	600000 – 699999
Month 36	VST 7	700000 – 799999
Month 48	VST 8	800000 – 899999
Month 60	VST 9	900000 – 999999
Month 72	VST 10	1000000 – 1099999
Month 84	VST 11	1100000 – 1199999

License Plate Number

from ADNI Barcode Label (NOT from Covance Label) - see Procedures Manual for further clarification

_____

Alzheimer's Disease Cooperative Study

ADCS

Sample Collection: Biomarker Samples

Visit: EMCI Subjects Baseline

ADNI PARTICIPANT NUMBER

			S				

ENTER THE FOLLOWING FIELDS ONLINE USING "METHOD OF CSF COLLECTION" ECRF.

Was CSF collected? ☐ Yes ☐ No

If No, please provide reason why the CSF was not collected:

- ☐ Illness
- ☐ Participant unavailable
- ☐ Participant unwilling
- ☐ Administrative problems
- ☐ Withdrawn consent
- ☐ Other (specify): _____

Examination Date ☐☐ ☐☐ ☐☐☐☐
MONTH DAY YEAR

For CSF collected, please answer the following **(ADNI Procedures recommend use of 22g Sprotte Needle with gravity)**: Needle used:

- ☐ 18g Quincke (sharp bevelled) needle
- ☐ 19g Quincke (sharp bevelled) needle
- ☐ 20g Quincke (sharp bevelled) needle
- ☐ 21g Quincke (sharp bevelled) needle
- ☐ 22g Quincke (sharp bevelled) needle
- ☐ 23g Quincke (sharp bevelled) needle
- ☐ 24g Quincke (sharp bevelled) needle
- ☐ 25g Quincke (sharp bevelled) needle
- ☐ 18g Sprotte (atraumatic) needle
- ☐ 19g Sprotte (atraumatic) needle
- ☐ 20g Sprotte (atraumatic) needle
- ☐ 21g Sprotte (atraumatic) needle
- ☐ **22g Sprotte (atraumatic) needle**
- ☐ 24g Sprotte (atraumatic) needle

Only Polypropylene tubes should be used for collection and shipment of CSF. If Polystyrene tubes are used, this is a protocol violation and must be noted in the protocol deviations log.

Type of collection tube used:
- ☐ Polypropylene
- ☐ Polystyrene (protocol violation)

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

If collected in polystyrene and shipped in polypropylene, please provide estimated amount of time CSF remained in collection tube.

☐☐☐ minutes

LP performed at the:
- ☐ L3-L4 Interspace
- ☐ L2-L3 Interspace
- ☐ ND/UNK

Patient Position:
- ☐ Sitting, leaned over (preferred)
- ☐ Lying, curled up on side
- ☐ ND/UNK

Alzheimer's Disease Cooperative Study

ADCS

Sample Collection: ApoE/GWAS/RNA Genotyping

Visit: EMCI Subjects Baseline

ADNI PARTICIPANT NUMBER ☐☐☐-S-☐☐☐☐

EXAMINER INITIALS ☐☐☐

EXAMINATION DATE ☐☐ MONTH ☐☐ DAY ☐☐☐☐ YEAR

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
☐ Male
☐ Female

Did the participant give consent to DNA testing? ☐ Yes ☐ No

Did the participant give consent to store and share their DNA Sample? ☐ Yes ☐ No

Was DNA sample collected (1 x 10 mL purple top EDTA tube)? ☐ Yes ☐ No

If yes, complete the following:

- Date of DNA collection:
  ☐☐ MONTH ☐☐ DAY ☐☐☐☐ YEAR
- Time of DNA collection (24hr clock):
  ☐☐ : ☐☐ **HH : MM**
- Phlebotomist Initials
  ☐☐☐

Volume of blood drawn into 10mL EDTA tube for DNA testing: ☐☐ **mL**

Date Fedexed: ☐☐ MONTH ☐☐ DAY ☐☐☐☐ YEAR

FedEx Tracking Number: _____

Alzheimer's Disease Cooperative Study

ADCS

Sample Collection: ApoE/GWAS/RNA Genotyping

Visit: EMCI Subjects Baseline

ADNI PARTICIPANT NUMBER ☐☐☐-S-☐☐☐☐

EXAMINER INITIALS ☐☐☐

EXAMINATION DATE ☐☐ MONTH ☐☐ DAY ☐☐☐☐ YEAR

Did the participant give consent to RNA testing? ☐ Yes ☐ No

Did the participant give consent to store and share their RNA Sample? ☐ Yes ☐ No

Were the PAXgene Blood RNA tubes the last tubes drawn? ☐ Yes ☐ No

If No, was a discard tube used? ☐ Yes ☐ No

Was RNA sample collected (3 x 2.5 mL PAXgene RNA tubes)? ☐ Yes ☐ No

If yes, complete the following:

- Date of RNA collection:

  ☐☐ MONTH ☐☐ DAY ☐☐☐☐ YEAR

- Time of RNA collection (24hr clock):

  ☐☐ : ☐☐ **HH : MM**

- Phlebotomist Initials

  ☐☐☐

Volume of blood drawn into 3 x 2.5 mL PAXgene RNA tubes: ☐☐ **mL**

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 ☐☐ MONTH ☐☐ DAY ☐☐☐☐ YEAR FedEx Tracking Number: _____

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)

_____

_____

_____

_____

_____

Alzheimer's Disease Cooperative Study

ADCS

Sample Collection: Immortalization Cell Collection

Visit: EMCI Subjects Baseline

ADNI PARTICIPANT NUMBER ☐☐☐-S-☐☐☐☐ | EXAMINER INITIALS ☐☐☐ | EXAMINATION DATE ☐☐ MONTH ☐☐ DAY ☐☐☐☐ YEAR

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? ☐ Yes ☐ No

Did the participant give consent to store and share their DNA Sample? ☐ Yes ☐ No

Was cell immortalization sample collected? ☐ Yes ☐ No

If yes, complete the following:

- Phlebotomist Initials: ☐☐☐
- Date of cell immortalization collection: ☐☐ MONTH ☐☐ DAY ☐☐☐☐ YEAR
- 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):

☐☐ mL

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)

_____

_____

_____

_____

Alzheimer's Disease Cooperative Study

ADCS

CSF - Local Lab Results

Visit: EMCI Subjects Baseline

ADNI PARTICIPANT NUMBER ___ S ____

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

Alzheimer's Disease Cooperative Study

ADCS

3T MRI Scan Information

Visit: EMCI Screening

ADNI PARTICIPANT NUMBER ☐☐☐-S-☐☐☐☐ EXAMINER INITIALS ☐☐☐ EXAMINATION DATE ☐☐ MONTH ☐☐ DAY ☐☐☐☐ YEAR

To be completed by Study Coordinator:

Study Coordinator Name: _____

Telephone #: _____

ADNI Participant Initials: ☐☐☐

Scheduled Date: ☐☐ MONTH ☐☐ DAY ☐☐☐☐ YEAR

To be completed by MRI Technologist *(If section above is incomplete please contact study coordinator for subject 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 ☐☐☐☐ YEAR

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? ☐ Yes ☐ No

Comments: _____

_____

_____

Scan #2: <u>Straight</u> 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? ☐ Yes ☐ No

Comments: _____

_____

_____

Alzheimer's Disease Cooperative Study

ADCS

3T MRI Scan Information

Visit: EMCI Screening

ADNI PARTICIPANT NUMBER

			S				

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? ☐ Yes ☐ No

Comments: _____

_____

_____

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? ☐ Yes ☐ No

Did the subject keep their eyes open? (MRI Tech: ask the subject right after the scan) ☐ Yes ☐ No

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? ☐ Yes ☐ No

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: _____

_____

_____

Alzheimer's Disease Cooperative Study

ADCS

3T MRI Scan Information

Visit: EMCI Screening

ADNI PARTICIPANT NUMBER

				S				
			–		–			

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? ☐ Yes ☐ No

Did the subject keep their eyes open? (MRI Tech: ask the subject right after the scan) ☐ Yes ☐ No

ASL Completed? ☐ Yes ☐ No

Comments: _____

_____

_____

GE Systems Only (with license agreement):
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*** *oblique the scanning slices.*

☐ *Not a GE Systems*

DTI Completed? ☐ Yes ☐ No

Comments: _____

_____

_____

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: ☐ Yes ☐ No

Comments: _____

_____

_____

Alzheimer's Disease Cooperative Study

ADCS

3T MRI Scan Information

Visit: EMCI Screening

ADNI PARTICIPANT NUMBER

[ ][ ][ ] S [ ][ ][ ][ ]

Scanner Malfunction: ☐ Yes ☐ No

Comments: _____

_____

_____

Other Protocol Variations: ☐ Yes ☐ No

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

☐ MOD

☐ Other: _____

☐ No

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?

☐ less than 6 hours ☐ 13-24 hours ☐ 49-72 hours

☐ 6-12 hours ☐ 25-48 hours ☐ more than 72 hours

Alzheimer's Disease Cooperative Study

ADCS

FDG-Pet Scan Information

Visit: EMCI Subjects Baseline

ADNI PARTICIPANT NUMBER ☐☐☐-S-☐☐☐☐

EXAMINER INITIALS ☐☐☐

EXAMINATION DATE ☐☐ MONTH ☐☐ DAY ☐☐☐☐ YEAR

To be completed by Study Coordinator:

Study Coordinator Name: _____

Telephone #: _____

ADNI Participant Initials: ☐☐☐

Scheduled Date:

☐☐ MONTH ☐☐ DAY ☐☐☐☐ YEAR

Was the scan conducted?

- ☐ Yes
- ☐ No

Reason why the scan was not conducted:

- ☐ Illness
- ☐ Participant unavailable
- ☐ Participant unwilling
- ☐ Administrative problems
- ☐ Withdrawn consent
- ☐ Other (specify) _____

Scan Date:

☐☐ Month ☐☐ Day ☐☐☐☐ Year

Technologist Initials

☐☐☐

Select one of the following 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

Alzheimer's Disease Cooperative Study

ADCS

FDG-Pet Scan Information

Visit: EMCI Subjects Baseline

ADNI PARTICIPANT NUMBER

[ ][ ][ ] 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) (*Proper Range: < 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**

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.

_____

_____

_____

_____

Alzheimer's Disease Cooperative Study

ADCS

FDG-Pet Scan Information

Visit: EMCI Subjects Baseline

ADNI PARTICIPANT NUMBER

			–	S	–				

SECTION II. SCAN PROTOCOL INFORMATION

Any variations from protocol during FDG uptake?

- ☐ Yes
- ☐ No

If Yes, describe: _____

Predefined Acquisition Protocol ID: _____

Which framing rate was used?

- ☐ 6 frames, 5 min/frame (6x300s)
- ☐ 2 scans, 15 min each (2 x 900s) (only for BioGraph scanners without list-mode)

If any deviations, describe: _____

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 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)

Alzheimer's Disease Cooperative Study

ADCS

FDG-Pet Scan Information

Visit: EMCI Subjects Baseline

ADNI PARTICIPANT NUMBER

				S				
			–		–			

If FORE/2D-OSEM, OSEM3D, or 3D Iterative:

Subsets:

- ☐ 14
- ☐ 16
- ☐ 20
- ☐ Other

If Other, specify: _____

Iterations:

- ☐ 4
- ☐ 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

Alzheimer's Disease Cooperative Study

ADCS

FDG-Pet Scan Information

Visit: EMCI 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

ADCS

AV-45 Pet Scan Information

Page 1 of 5

Visit: EMCI Subjects Baseline

ADNI PARTICIPANT NUMBER ___ ___ ___ - S - ___ ___ ___ ___

EXAMINER INITIALS ___ ___ ___

EXAMINATION DATE ___ ___ (MONTH) ___ ___ (DAY) ___ ___ ___ ___ (YEAR)

To be completed by Study Coordinator:

Study Coordinator Name: _____

Telephone #: _____

ADNI Participant Initials: ___ ___ ___

Scheduled Date: ___ ___ (MONTH) ___ ___ (DAY) ___ ___ ___ ___ (YEAR)

Was the scan conducted?

- ☐ Yes
- ☐ No

  Reason why the scan was not conducted:

  - ☐ Illness
  - ☐ Participant unavailable
  - ☐ Participant unwilling
  - ☐ Administrative problems
  - ☐ Withdrawn consent
  - ☐ Other (specify) _____

Scan Date: ___ ___ (MONTH) ___ ___ (DAY) ___ ___ ___ ___ (YEAR)

Technologist Initials ___ ___ ___

Select one of the following 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

Alzheimer's Disease Cooperative Study

ADCS

AV-45 Pet Scan Information

Visit: EMCI Subjects Baseline

ADNI PARTICIPANT NUMBER

[ ][ ][ ] – S – [ ][ ][ ][ ]

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**

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.

Alzheimer's Disease Cooperative Study

ADCS

AV-45 Pet Scan Information

Visit: EMCI Subjects Baseline

ADNI PARTICIPANT NUMBER

				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: _____

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)

Alzheimer's Disease Cooperative Study

ADCS

AV-45 Pet Scan Information

Visit: EMCI Subjects Baseline

ADNI PARTICIPANT NUMBER

				S				
			–		–			

If FORE/2D-OSEM, OSEM3D, or 3D Iterative:

Subsets:

- ☐ 14
- ☐ 16
- ☐ 20
- ☐ Other

If Other, specify: _____

Iterations:

- ☐ 4
- ☐ 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

Alzheimer's Disease Cooperative Study

ADCS

AV-45 Pet Scan Information

Visit: EMCI 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 AV-45 scan?

- ☐ Yes
- ☐ No

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

- ☐ 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

ADCS

AV-45 Pre and Post Injection Vitals Form

Visit: EMCI Subjects Baseline

ADNI PARTICIPANT NUMBER ☐☐☐-S-☐☐☐☐

EXAMINER INITIALS ☐☐☐

EXAMINATION DATE ☐☐ MONTH ☐☐ DAY ☐☐☐☐ YEAR

Was scan conducted?

☐ Yes

☐ 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: ☐ Oral ☐ Tympanic ☐ Other

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 _____

Alzheimer's Disease Cooperative Study

ADCS

AV-45 24-48 Hour Follow-Up

Visit: EMCI Subjects Baseline

ADNI PARTICIPANT NUMBER ☐☐☐-S-☐☐☐☐ | EXAMINER INITIALS ☐☐☐ | EXAMINATION DATE ☐☐ MONTH ☐☐ DAY ☐☐☐☐ 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
- ☐ No

If any **Adverse Events** are reported, complete the AE eCRF page.

Alzheimer's Disease Cooperative Study

ADCS

Protocol Deviations Log Form

Visit: EMCI Screening

ADNI PARTICIPANT NUMBER ☐☐☐-S-☐☐☐☐

EXAMINER INITIALS ☐☐☐

EXAMINATION DATE ☐☐ MONTH ☐☐ DAY ☐☐☐☐ YEAR

Deviation applies to (*Any clear deviation from the protocol procedures identified prior to its initiation or implementation will result in the participant being screen failed or discontinued from the study*):

- ☐ Protocol Violation: A protocol deviation that was not reviewed by the Project Director/Coordinating Center prior to its initiation or implementation.
- ☐ Protocol Clarification: A potential protocol deviation that requires review and confirmation from the Project Director/Coordinating Center as to whether it is, in fact, a deviation.

Please select the most appropriate description:

1. ☐ Inclusion Criteria (provide item number below)
2. ☐ Exclusion Criteria (provide item number below)
3. ☐ Out of Window Baseline Visit
4. ☐ Initiation/change of cholinesterase inhibitor or memantine
5. ☐ Started Excluded Medication (does not include Cholinesterase Inhibitor or Memantine)
6. ☐ Missed Visit
7. ☐ Missed Vital Signs
8. ☐ Deviation from vitals collection procedures
9. ☐ Missed Screening Laboratory Tests
10. ☐ Screening laboratory tests done outside the protocol-required time
11. ☐ Deviation from blood sample collection procedures (Biomarkers)
12. ☐ Deviation from blood sample collection procedures (ApoE/GWAS/RNA Genotyping)
13. ☐ Deviation from blood sample collection procedures (Cell Immortalization)
14. ☐ Deviation from CSF Collection Procedures
15. ☐ Subject/Study Partner (or legal representative, if applicable) did not sign the initial consent form
16. ☐ Subject/Study Partner (or legal representative, if applicable) did not sign updated/renewal consent form (if applicable)
17. ☐ Subject data reported prior to signed consent
18. ☐ Out-of-window Visit (Does not include out-of-window baseline visit)
19. ☐ Out-of-window MRI
20. ☐ Out-of-window FDG PET
21. ☐ Out-of-window 18F-AV-45 PET
22. ☐ Out of mCi dose range FDG
23. ☐ Out of mCi dose range AV-45
24. ☐ Missed LP Follow-Up Call
25. ☐ Missed AV-45 Follow-Up Call
26. ☐ Other

If Other, Specify: _____

_____

_____

Alzheimer's Disease Cooperative Study

ADCS

Protocol Deviations Log Form

Visit: EMCI Screening

ADNI PARTICIPANT NUMBER

			–	S	–			

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:

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):

_____

_____

_____

_____

_____

_____

Alzheimer's Disease Cooperative Study

ADCS

Adverse Events and Hospitalizations - Log

Visit: EMCI Screening

ADNI PARTICIPANT NUMBER ☐☐☐-S-☐☐☐☐

EXAMINER INITIALS ☐☐☐

EXAMINATION DATE ☐☐ MONTH ☐☐ DAY ☐☐☐☐ YEAR

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

Alzheimer's Disease Cooperative Study

ADCS

Adverse Events and Hospitalizations - Log

Visit: EMCI Screening

ADNI PARTICIPANT NUMBER

				S				
			–					

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):

☐ Definitely ☐ Possibly ☐ 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			

Alzheimer's Disease Cooperative Study

ADCS

Adverse Events and Hospitalizations - Log

Visit: EMCI Screening

ADNI PARTICIPANT NUMBER

				S				

If hospitalized, Admission Date:

MONTH DAY YEAR

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 trauma reveal additional AEs or symptoms such as light-headedness, poor balance, visual disturbance, etc., record these as additional AEs and briefly describe the scenario in the comments section under one of the related symptoms)*:

_____

_____

_____

_____

_____

Clinician's Signature (required) _____ **Date** _____