Alzheimer's Disease Neuroimaging Initiative
ADNI

Worksheet Packet

SCHEDULE OF EVENTS (NORMAL SUBJECTS)

Visit number	1	2	3	4	5	6	7	8	9	10
Visit name	Screen	Baseline								
Time (months)	0	1	6	12	18	24	30	36	42^3	48^3
Explain Study	x								x	
Obtain Consent	x								x	
Demographics, Family History, Inclusion and Exclusion Criteria	x									
Medical History, Physical Exam, Neurological Exam, Hachinski	x									
Vital Signs	x	x	x	x		x		x		x
Screening Labs	x									
APOE	x									
American National Adult Reading Test		x								
Mini Mental State Examination	x		x	x		x		x		x
Logical Memory I and II	x			x		x		x		x
Digit Span		x	x	x		x		x		x
Category Fluency		x	x	x		x		x		x
Trails A & B		x	x	x		x		x		x
Digit Symbol		x	x	x		x		x		x
Boston Naming Test		x	x	x		x		x		x
Auditory Verbal Learning Test		x	x	x		x		x		x
Geriatric Depression Scale	x			x		x		x		x
Clock drawing		x	x	x		x		x		x
Neuropsychiatric Inventory Q		x	x	x		x		x		x
ADAS-Cog		x	x	x		x		x		x
Clinical Dementia Rating Scale	x		x	x		x		x		x
Activities of Daily Living (FAQ)		x	x	x		x		x		x
Collect and process biomarkers		x^1	x	x		x		x		x
Concomitant Medications	x	x	x	x		x		x		x
Subject Payments	x	x	x	x		x		x		x
Phone Contact					x		x		x	
Adverse Events	x	x	x	x	x	x	x	x	x	x
Diagnostic Summary	x	x	x	x		x		x		x
MRI (1.5 T) (100%)	x			x	x		x		x		x
MRI (3 T) (25%)		x	x	x		x		x		
PET (50%)		x	x	x		x		x		x
LP (minimum of 20%)		x		x		x^2		x^2		x^3

[1] Includes blood draw for Immortalized cell lines
[2] Optional LP for subjects consenting to the CSF extension study
[3] Additional years for follow-up are planned, depending on funding, IRB approval and consent of participants. This includes optional LP for subjects consenting to the CSF extension study.

SCHEDULE OF EVENTS (MCI SUBJECTS)

Visit number	1	2	3	4	5	6	7	8	9	10
Visit name	Screen	Baseline								
Time (months)	0	1	6	12	18	24	30	36	42[3]	48[3]
Explain study	x								x[3]	
Obtain consent	x								x[3]	
Demographics, Family History, Inclusion and Exclusion Criteria	x									
Medical History, Physical Exam, Neurological Exam, Hachinski	x									
Vital Signs	x	x	x	x	x	x		x		x
Screening labs	x									
APOE	x									
American National Adult Reading Test		x								
Mini Mental State Examination	x		x	x	x	x		x		x
Logical Memory I and II	x			x		x		x		x
Digit Span		x	x	x	x	x		x		x
Category Fluency		x	x	x	x	x		x		x
Trails A & B		x	x	x	x	x		x		x
Digit symbol		x	x	x	x	x		x		x
Boston Naming Test		x	x	x	x	x		x		x
Auditory Verbal Learning Test		x	x	x	x	x		x		x
Geriatric Depression Scale	x			x		x		x		x
Clock drawing		x	x	x	x	x		x		x
Neuropsychiatric Inventory Q		x	x	x	x	x		x		x
ADAS-Cog		x	x	x	x	x		x		x
Clinical Dementia Rating Scale	x		x	x	x	x		x		x
Activities of Daily Living(FAQ)		x	x	x	x	x		x		x
Collect and process biomarkers		x[1]	x	x	x	x		x		x
Concomitant Medications	x	x	x	x	x	x		x		x
Subject payments	x	x	x	x	x	x		x		x
Phone contact							x		x	
Adverse events	x	x	x	x	x	x	x	x	x	x
Diagnostic Summary	x	x	x	x	x	x		x		x
MRI (1.5 T) (100%)	x		x	x	x	x		x		x
MRI (3 T) (25%)		x	x	x	x	x		x		
PET (50%)		x	x	x	x	x		x		
LP (minimum of 20%)		x		x		x[2]				x[3]

[1]Includes blood draw for Immortalized cell lines

SCHEDULE OF EVENTS (AD SUBJECTS)

Visit number	1	2	3	4	5	6	7
Visit name	Screen	Baseline					
Time (months)	0	1	6	12	18	24	36[3]
Explain study	x						x
Obtain consent	x						x
Demographics, Family History, Inclusion and Exclusion Criteria	x						
Medical History, Physical Exam, Neurological Exam, Hachinski	x						
Vital Signs	x	x	x	x		x	x
Screening labs	x						
APOE	x						
American National Adult Reading Test		x					
Mini Mental State Examination	x		x	x		x	x
Logical Memory I and II	x			x		x	x
Digit Span		x	x	x		x	x
Category Fluency		x	x	x		x	x
Trails A & B		x	x	x		x	x
Digit symbol		x	x	x		x	x
Boston Naming Test		x	x	x		x	x
Auditory Verbal Learning Test		x	x	x		x	x
Geriatric Depression Scale	x			x		x	x
Clock drawing		x	x	x		x	x
Neuropsychiatric Inventory Q		x	x	x		x	x
ADAS-Cog		x	x	x		x	x
Clinical Dementia Rating Scale	x		x	x		x	x
Activities of Daily Living(FAQ)		x	x	x		x	x
Collect and process biomarkers		x[1]	x	x		x	x
Concomitant Medications	x	x	x	x		x	x
Subject payments	x	x	x	x		x	x
Phone contact					x		
Adverse events	x	x	x	x	x	x	x
Diagnostic Summary	x	x	x	x		x	x
MRI (1.5 T) (100%)	x		x	x		x	
MRI (3 T) (25%)		x	x	x		x	
PET (50%)		x	x	x		x	
LP (minimum of 20%)		x		x		x[2]	x[3]

Examiner Initials

Examination Date

Month   Day   Year

Is this a rescreen?

Answer "Yes" if participant has previously been assigned a different ADNI ID.

☐ Yes

☐ No

If Yes, what was the participant's initial ID number?

Format: XXX_S_YYYY

Participant Demographic Information

Participant: ⬜

Participant ID

Visit: Screening

Instructions:
At Screening Visit, all questions must be answered. At subsequent visits, this form need only be completed if a change to Participant's Marital Status, Most recent occupation, or Type of residence has occurred. At that time, only the information that has changed needs to be entered, all other questions may be left blank.

Examiner Initials
⬜

Examination Date
⬜⬜ ⬜⬜ ⬜⬜⬜⬜
Month Day Year

Information Source
☐ Participant Visit
☐ Telephone Call

1. Participant Gender
☐ Male
☐ Female

2. Participant Date of Birth
⬜⬜ ⬜⬜ ⬜⬜⬜⬜
Month Day Year

3. Participant Handedness
☐ Right
☐ Left

4. Participant Marital Status
☐ Married
☐ Widowed
☐ Divorced
☐ Never married
☐ Unknown

5. Participant Education
     NOTE: Refer to the Procedures Manual for instructions on reporting years of education.

If less than 6 years...
     5a. Does the participant have a work history sufficient to exclude mental retardation?

          NOTE: If No, the participant must be excluded from the study.
     ☐ Yes
     ☐ No

6. Participant Occupation

6a. Primary occupation during most of adult life
⬜

6b. Most recent occupation
⬜

7. Participant Retired?
☐ Yes
☐ No

Retirement Date
⬜⬜ ⬜⬜ ⬜⬜⬜⬜
Month Day Year

8. Type of Participant residence
    - ☐ House
    - ☐ Condo/Co-op (owned)
    - ☐ Apartment (rented)
    - ☐ Mobile Home
    - ☐ Retirement Community
    - ☐ Assisted Living
    - ☐ Skilled Nursing Facility
    - ☐ Other (specify)

    If Other, specify:

9. Language to be used for testing the Participant
    NOTE: Only one may be checked and must remain same throughout study.
    - ☐ English
    - ☐ Spanish

10. Participant's Primary Language
    - ☐ English
    - ☐ Spanish
    - ☐ Other (specify)

    If Other, specify:

11. Year of onset of Alzheimer's disease symptoms (best estimate)
    NOTE: Field is not applicable for MCI and NL participants.

12. Ethnic Category
    - ☐ Hispanic or Latino
    - ☐ Not Hispanic or Latino
    - ☐ Unknown

13. Racial Categories
    - ☐ American Indian or Alaskan Native
    - ☐ Asian
    - ☐ Native Hawaiian or Other Pacific Islander
    - ☐ Black or African American
    - ☐ White
    - ☐ More than one race
    - ☐ Unknown

Instructions:
At Visit 1, all questions must be answered. At subsequent visits,
this form need only be completed if the Participant's Study Partner
changes.

Examiner Initials
[   ]

Examination Date
[ ][ ] [ ][ ] [ ][ ][ ][ ]
Month   Day   Year

1. Study Partner Initials
[   ]

2. Study Partner Gender
☐ Male
☐ Female

3. Study Partner Date of Birth
[ ][ ] [ ][ ] [ ][ ][ ][ ]
Month   Day   Year

4. Study Partner Marital Status
☐ Married
☐ Widowed
☐ Divorced
☐ Never married
☐ Unknown

5. Study Partner Education
NOTE: Refer to the Procedures Manual for instructions on reporting years of education.

6. Study Partner Occupation

6a. Primary occupation during most of adult life
[   ]

6b. Most recent occupation
[   ]

7. Study Partner Retired?
☐ Yes
☐ No

Study Partner Retirement Date
If Month and/or Day are unknown, enter '- -' in their place. A valid Year must be provided.
[ ][ ] [ ][ ] [ ][ ][ ][ ]
Month   Day   Year

8. Relationship of the Study Partner to the Participant
    - ☐ Husband
    - ☐ Wife
    - ☐ Son
    - ☐ Daughter
    - ☐ Son-in-Law
    - ☐ Daughter-in-Law
    - ☐ Other relative (specify)
    - ☐ Friend/companion
    - ☐ Paid caregiver (specify)
    - ☐ Other (specify)

    If Other relative, Paid Caregiver, or Other, specify:
    _____

9. How many hours per week does the Study Partner spend with the Participant?
    (Range 1-168)

    _____ **hours**

10. Do the Study Partner and Participant live together?
    - ☐ Yes
    - ☐ No

11. Language to be used for testing the Study Partner
    NOTE: Only one may be checked, and must remain the same throughout the study.
    - ☐ English
    - ☐ Spanish

Family History Questionnaire

Participant: [_____]

Participant ID

Visit: Screening

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 click the "Details"
button to provide information about his/her history of dementia.

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

Examiner initials

[_____]

Examination Date

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

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	Alzheimer's Disease
☐ Yes	☐ Yes
☐ No	☐ No

2. Father

Dementia	Alzheimer's Disease
☐ Yes	☐ Yes
☐ No	☐ No

3. Does the participant have any siblings?
If yes, please provide additional information by clicking "Details" below.
☐ Yes
☐ No

Details

Family History Questionnaire Subtable

Participant: [_____]

Participant ID

Visit: Screening

Examiner Initials

[_____]

Examination Date

[__][__][__][__][__][__]

Month   Day   Year

Sibling

Gender	Dementia	Alzheimer's Disease
☐ Male	☐ Yes	☐ Yes
☐ Female	☐ No	☐ No

Vital Signs

Participant: [   ]

Participant ID

Visit: Screening

Instructions:
Units used to report weight and temperature must be consistent
across all visits for each participant.

NOTE: An exception (to Inclusion #19b) is required if any Screening
vitals are not obtained.

Examiner Initials
[   ]

Examination Date
[ ][ ][ ][ ][ ][ ][ ]
Month   Day   Year

1a. Weight
[   ]

1b. Weight Units
☐ pounds
☐ kilograms

2a. Height
[   ]

2b. Height Units
☐ inches
☐ centimeters

3. Seated Blood Pressure
Systolic - mmHg   Diastolic - mmHg

4. Seated Pulse Rate (per minute)

5. Respirations (per minute)

6a. Temperature
[   ] **degrees**

6b. Temperature Source
☐ Oral
☐ Tympanic
☐ Other

6c. Temperature Units
☐ Fahrenheit
☐ Celsius

7. Comments regarding vital signs:
[   ]

Center: _____

Alzheimer's Disease Neuroimaging Initiative

Concurrent Medications Log

ADNI Subject Number

___ ___ _S_ ___ ___ ___ ___

Examiner Initials

___ ___ ___

Check box corresponding to visit of last update:

Examination Date

Month	Day	Year

Visits

☐ SC ☐ BL ☐ M06 ☐ M12 ☐ M18 ☐ M24 ☐ M30 ☐ M36

☐ M42 ☐ M48

INSTRUCTIONS: At screening, list all medications (prescription and over-the-counter, including vitamins and herbal supplements) taken within the past three months. All conditions requiring medications should be listed on the Medical History. If medication will be continued past the screening date, check the "Continuing past screening" box. Update the form at every visit. If the medications continue at the end of the protocol or Treatment Discontinuation Visit, check the "Continuing at end of study" box.

☐ **No medication 3 months prior to the screening visit**

Medication	Continuing past screening	Dose/Freq/Route*	Date Began† Month/Day/Year	Date Ended† Month/Day/Year	Reason Prescribed	Comments	Continuing at Final Visit
_____	☐	__/__/__			_____	_____	☐
_____	☐	__/__/__			_____	_____	☐
_____	☐	__/__/__			_____	_____	☐
_____	☐	__/__/__			_____	_____	☐
_____	☐	__/__/__			_____	_____	☐
_____	☐	__/__/__			_____	_____	☐
_____	☐	__/__/__			_____	_____	☐
_____	☐	__/__/__			_____	_____	☐
_____	☐	__/__/__			_____	_____	☐

* See procedures manual for further clarification

Center: _____

Alzheimer's Disease Neuroimaging Initiative

Medical History

ADNI Subject Number

□□ _S_ □□□□

Examiner Initials

□□□

Examination Date

□□ □□ □□
Month Day Year

INSTRUCTIONS: Indicate whether or not the subject has a clinically significant history of problems in any of the areas listed below. **If Yes,** indicate whether the problem is **Current** and give details, including the best estimate of date. **If Current,** indicate whether the problem is **Stable.** If the subject is currently taking medication for a condition, the condition should be recorded below and **both Yes and Current boxes** should be checked.

Review of Systems

	No (0)	Yes (1)	Current	Stable	Details (*must* be answered if "Yes" is checked)
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	□	□	□	□	
14. Alcohol Abuse	□	□	□	□	
15. Drug Abuse	□	□	□	□	
16. Smoking	□	□	□	□	*(indicate type, packs per day, number of years, date ceased)*
17. Malignancy	□	□	□	□	
18. Major Surgical Procedures	□	□	□	□	
19. Other	□	□	□	□	
20. General Comments					

Instructions:
If any item is abnormal, provide a brief description or comment about the finding. If there are no other findings, please check #12 (Other) as "Normal".

Examiner Initials

[   ]

Examination Date

☐ ☐ ☐ ☐ ☐ ☐ ☐
Month Day Year

1. General Appearance
   ☐ Normal
   ☐ Abnormal

   Details
   (Must be provided if Abnormal.)
   [   ]

2. Head, Eyes, Ears, Nose and Throat
   ☐ Normal
   ☐ Abnormal

   Details
   (Must be provided if Abnormal.)
   [   ]

3. Neck
   ☐ Normal
   ☐ Abnormal

   Details
   (Must be provided if Abnormal.)
   [   ]

4. Chest
   ☐ Normal
   ☐ Abnormal

   Details
   (Must be provided if Abnormal.)
   [   ]

5. Heart
   ☐ Normal
   ☐ Abnormal

   Details
   (Must be provided if Abnormal.)
   [   ]

6. Abdomen
   ☐ Normal
   ☐ Abnormal

   Details
   (Must be provided if Abnormal.)
   [   ]

7. Extremities
   ☐ Normal
   ☐ Abnormal

   Details
   (Must be provided if Abnormal.)
   [   ]

8. Edema
   ☐ Normal
   ☐ Abnormal

   Details
   (Must be provided if Abnormal.)
   [   ]

9. Peripheral Vascular
   ☐ Normal
   ☐ Abnormal

   Details
   (Must be provided if Abnormal.)
   [   ]

10. Skin and Appendages
    ☐ Normal
    ☐ Abnormal

    Details
    (Must be provided if Abnormal.)
    [   ]

11. Musculoskeletal
    ☐ Normal
    ☐ Abnormal

    Details
    (Must be provided if Abnormal.)
    [   ]

12. Other   Details
    ☐ Normal   *(Must be provided if Abnormal.)*
    ☐ Abnormal

13. General Comments

14. Based on the Physical Examination, clinician must check appropriate box below:
    *NOTE: If the participant is not eligible, he/she may not be enrolled without an exception from
    the Project Director.*
    ☐ Findings consistent with eligibility for study
    ☐ Participant is not eligible for study

Clinician's Signature:_____ Date:_____

Neurological Exam

Participant: [   ]
Participant ID

Visit: Screening

Instructions:
If any item is present or abnormal, provide a brief description
or comment about the finding. If there are no other findings,
please check #12 (Other) as "Normal".

Examiner Initials
[   ]

Examination Date
[ ][ ][ ][ ][ ][ ][ ]
Month   Day   Year

1. Significant Visual Impairment
   ☐ Absent
   ☐ Present

   Details
   (Must be provided if Present.)
   [   ]

2. Significant Auditory Impairment
   ☐ Absent
   ☐ Present

   Details
   (Must be provided if Present.)
   [   ]

3. Tremor
   ☐ Absent
   ☐ Present

   Details
   (Must be provided if Present.)
   [   ]

4. Level of Consciousness
   ☐ Normal
   ☐ Abnormal

   Details
   (Must be provided if Abnormal.)
   [   ]

5. Cranial Nerves
   ☐ Normal
   ☐ Abnormal

   Details
   (Must be provided if Abnormal.)
   [   ]

6. Motor Strength
   ☐ Normal
   ☐ Abnormal

   Details
   (Must be provided if Abnormal.)
   [   ]

7a. Cerebellar - Finger to Nose
   ☐ Normal
   ☐ Abnormal

   Details
   (Must be provided if Abnormal.)
   [   ]

7b. Cerebellar - Heel to Shin
   ☐ Normal
   ☐ Abnormal

   Details
   (Must be provided if Abnormal.)
   [   ]

8. Sensory
   ☐ Normal
   ☐ Abnormal

   Details
   (Must be provided if Abnormal.)
   [   ]

9. Deep Tendon Reflexes
   ☐ Normal
   ☐ Abnormal

   Details
   (Must be provided if Abnormal.)
   [   ]

10. Plantar Reflexes
   ☐ Normal
   ☐ Abnormal

   Details
   (Must be provided if Abnormal.)
   [   ]

11. Gait
    ☐ Normal
    ☐ Abnormal

    Details
    (Must be provided if Abnormal.)
    [   ]

12. Other
    ☐ Normal
    ☐ Abnormal

    Details
    (Must be provided if Abnormal.)
    [   ]

13. General Comments

    [   ]

14. Based on Neurological Examination, clinician must check appropriate box below:
    NOTE: If the participant is not eligible, he/she may not be enrolled without an exception from the Project Director.
    ☐ Findings consistent with eligibility for study
    ☐ Participant is not eligible for study

Clinician's Signature:_____ Date:_____

Baseline Symptoms Checklist was conducted only at the baseline 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 baseline on the Baseline Symptoms Checklist) OR if the condition noted at baseline had worsen in chronicity or severity it was to be documented as an adverse event.

Baseline Symptoms Checklist

Participant:

Participant ID

Visit: Baseline

Instructions:
Considering the preceding three months, check "Absent" or "Present"
for each symptom listed below. If "Present," click the "Details"
button and provide the required information on the Documentation
of Baseline Symptoms Log.

If a diagnosis is made between screen and baseline, the diagnosis
should be documented under question #28 (Other) and entered in
the Documentation of Baseline Symptoms Log. Do not check symptoms
associated with the diagnosis.

Examiner Initials

Examination Date

Month Day Year

1. Nausea
    ☐ Absent
    ☐ Present

Details

2. Vomiting
    ☐ Absent
    ☐ Present

Details

3. Diarrhea
    ☐ Absent
    ☐ Present

Details

4. Constipation
    ☐ Absent
    ☐ Present

Details

5. Abdominal discomfort
    ☐ Absent
    ☐ Present

Details

6. Sweating
    ☐ Absent
    ☐ Present

Details

7. Dizziness
    ☐ Absent
    ☐ Present

Details

8. Low energy
    ☐ Absent
    ☐ Present

Details

9. Drowsiness
    ☐ Absent
    ☐ Present

Details

10. Blurred vision
    ☐ Absent
    ☐ Present

Details

11. Headache
    ☐ Absent
    ☐ Present

Details

12. Dry mouth
    ☐ Absent
    ☐ Present

Details

13. Shortness of breath
    ☐ Absent
    ☐ Present

Details

14. Coughing
    ☐ Absent
    ☐ Present

Details

15. Palpitations
    ☐ Absent
    ☐ Present

Details

16. Chest pain
    ☐ Absent
    ☐ Present

Details

17. Urinary discomfort (e.g., burning)
    ☐ Absent
    ☐ Present

Details

18. Urinary frequency
    ☐ Absent
    ☐ Present

Details

19. Ankle swelling
    ☐ Absent
    ☐ Present

Details

20. Musculoskeletal pain
    ☐ Absent
    ☐ Present

Details

21. Rash
☐ Absent
☐ Present

Details

22. Insomnia
☐ Absent
☐ Present

Details

23. Depressed mood
☐ Absent
☐ Present

Details

24. Crying
☐ Absent
☐ Present

Details

25. Elevated mood
☐ Absent
☐ Present

Details

26. Wandering
☐ Absent
☐ Present

Details

27. Fall
☐ Absent
☐ Present

Details

28. Other
☐ Absent
☐ Present

Details

Center: _____

Alzheimer's Disease Neuroimaging Initiative

Documentation of Baseline Diagnoses and Symptoms Log

ADNI Subject Number

____ ____ _ S _ ____ ____ ____ ____

Examiner Initials: ____ ____ ____

Examination Date: Month ____ ____ Day ____ ____ Year ____ ____

Check box corresponding to visit of last update:

Visits

| BL ☐ | M6 ☐ | M12 ☐ | M18 ☐ | M24 ☐ | M30 ☐ | M36 ☐ |
| M42 ☐ | M48 ☐ |

Instructions: At Baseline, record all symptoms marked Present on the Baseline Diagnoses and Symptoms Checklist. At subsequent visits, the subject should be queried about the status of each symptom. **All new symptoms, or baseline symptoms that have worsened in chronicity or severity, must be recorded on an Adverse Events case report form.**

Symptom Number	Description	Severity	Chronicity	Date of Onset	Date Ceased
☐ ☐		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: _____

Diagnosis and Symptoms Checklist

Participant:

[   ]

Participant ID

Visit: Month 12

Instructions:
Select "Absent" or "Present" for each symptom or diagnosis listed
below. If a diagnosis has been made, the diagnosis should be documented
under question #28 (Other/Diagnosis). Do not check symptoms associated
with the diagnosis. All new symptoms/diagnoses, or symptoms/diagnoses
present at baseline that have worsened in chronicity or severity,
must be reported as Adverse Events.

Examiner Initials

[   ]

Examination Date

[ ][ ][ ][ ][ ][ ][ ]

Month   Day   Year

1. Nausea
    ☐ Absent
    ☐ Present

Details

2. Vomiting
    ☐ Absent
    ☐ Present

Details

3. Diarrhea
    ☐ Absent
    ☐ Present

Details

4. Constipation
    ☐ Absent
    ☐ Present

Details

5. Abdominal discomfort
    ☐ Absent
    ☐ Present

Details

6. Sweating
    ☐ Absent
    ☐ Present

Details

7. Dizziness
    ☐ Absent
    ☐ Present

Details

8. Low energy
    ☐ Absent
    ☐ Present

Details

9. Drowsiness
   ☐ Absent
   ☐ Present

Details

10. Blurred vision
   ☐ Absent
   ☐ Present

Details

11. Headache
   ☐ Absent
   ☐ Present

Details

12. Dry mouth
   ☐ Absent
   ☐ Present

Details

13. Shortness of breath
   ☐ Absent
   ☐ Present

Details

14. Coughing
   ☐ Absent
   ☐ Present

Details

15. Palpitations
   ☐ Absent
   ☐ Present

Details

16. Chest pain
   ☐ Absent
   ☐ Present

Details

17. Urinary discomfort (e.g., burning)
   ☐ Absent
   ☐ Present

Details

18. Urinary frequency
   ☐ Absent
   ☐ Present

Details

19. Ankle swelling
   ☐ Absent
   ☐ Present

Details

20. Muscloskeletal pain
   ☐ Absent
   ☐ Present

Details

21. Rash
    ☐ Absent
    ☐ Present

Details

22. Insomnia
    ☐ Absent
    ☐ Present

Details

23. Depressed mood
    ☐ Absent
    ☐ Present

Details

24. Crying
    ☐ Absent
    ☐ Present

Details

25. Elevated mood
    ☐ Absent
    ☐ Present

Details

26. Wandering
    ☐ Absent
    ☐ Present

Details

27. Fall
    ☐ Absent
    ☐ Present

Details

28. Other/Diagnosis
    ☐ Absent
    ☐ Present

Details

If Other symptoms/diagnosis, specify:

Details

Adverse Events/Hospitalizations - Log

Participant:

[   ]

Participant ID

Visit: Screening

Log Instructions:
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.

At each visit, the Participant should be asked about the status of each
Adverse Event.To add a new record, click on the "Add a new record" button
below. To update a record, click on the corresponding record number link.

Examiner Initials

[   ]

Examination Date

☐☐ ☐☐ ☐☐☐☐
Month   Day   Year

Event (Diagnosis or Symptom if diagnosis is not known)

* * If a diagnosis is reported here, DO NOT report the associated symptoms as seperate Adverse*

Events. Record associated symptoms under the Comments section of this form.

* * If an event description can be clarified with a keyword, please include that in parenthesis*

in the Event field (Example: "repeatedly combs hair (behavior)")

[   ]

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

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

Adverse Events/Hospitalizations - Log

Participant: [   ]
                     Participant ID

Visit: Screening

Severity
    □ Mild
    □ Moderate
    □ Severe

Serious?   Check here if:
    If Yes, complete this form to the best of your   □ SAE prior to Baseline Visit
    ability within 24 hours. Submitting this form
    will trigger notifications to the Project Director
    and your clinical monitor. Refer to the Procedures
    Manual for further instructions.
    □ Yes
    □ No

    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

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

Adverse Events/Hospitalizations - Log

Participant:

<div style="text-align:center">Participant ID</div>

Visit: Screening

Admit 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:_____  Date:_____
```

Modified Hachinski

Participant:

Visit: Screening

Instructions:
Select "Absent" or "Present" for each of the clinical features
of cognitive impairment listed below.

Examiner Initials

Examination Date

Month   Day   Year

1. Abrupt Onset of Dementia
   ☐ Present - 2 points
   ☐ Absent

2. Stepwise Deterioration of Dementia
   ☐ Present - 1 point
   ☐ Absent

3. Somatic Complaints
   ☐ Present - 1 point
   ☐ Absent

4. Emotional Incontinence
   ☐ Present - 1 point
   ☐ Absent

5. History of Hypertension
   ☐ Present - 1 point
   ☐ Absent

6. History of Stroke
   ☐ Present - 2 points
   ☐ Absent

7. Focal Neurologic Symptoms
   ☐ Present - 2 points
   ☐ Absent

8. Focal Neurologic Signs
   ☐ Present - 2 points
   ☐ Absent

TOTAL SCORE
   Sum the values assigned to the items answered "Present" (Range: 0-12)
   NOTE: Total score must be less than or equal to 4 for the participant to be included in the study.

ADNI - Execution Phase (ADNI)
Clinical Laboratory Tests

Participant: [   ]
Participant ID

Visit: Screening

Instructions:
Refer to the Procedures Manual for detailed instructions.

Examiner Initials
[   ]

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:_____

ApoE Genotyping - Draw Data

Participant: ⬚

Participant ID

Visit: Screening

Instructions:
Blood drawn for APOE genotyping must be received by the UPenn
Biomarker repository within 24 hours of collection. The sample
must be maintained at room temperature and shipped by Federal
Express - Priority Overnight to UPENN at ambient temperature.

NOTE: If blood is draw on Friday, be sure to check "Saturday Delivery"
on the FedEx form and apply orange "Saturday Delivery" labels
to the package.

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.

Phlebotomist Initials
⬚

Date of Blood Draw   Time of Blood Draw
⬚⬚ ⬚⬚ ⬚⬚⬚   ⬚
Month   Day   Year

Date Fedexed   Fedex Tracking Number
For UPENN sites, please provide the date delivered.
⬚⬚ ⬚⬚ ⬚⬚⬚
Month   Day   Year

Volume of Blood Drawn into Lavendar Top Tube

6 digit License Plate Number
from ADNI Barcode Label (NOT the Covance label) - see Procedures Manual for more information
⬚

Biomarker Samples

Participant: [   ]
                    Participant ID

Visit: Baseline

Instructions:
Begin by printing out a PDF of the online Biomarker Samples Form
and completing the Sample Identification Labels. The bar code
label must be placed on the transfer tube prior to freezing.
Fluids should be collected in the following order:
* Biomarker plain red-top tubes (2 blood collection tubes)
* Biomarker lavender-top (2 blood collection tubes)
* Urine collection container
* CSF Collection(if applicable)
Complete the Biomarker Samples Form online before shipping samples.
Print a PDF of the completed form and include a copy 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
☐ Urine
☐ CSF
☐ None
If CSF collected, please answer the following:
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   Time of Collection
☐☐☐☐☐☐☐☐   [   ]
Month   Day   Year

Phlebotomist Initials
[   ]

CSF Collector Initials
[   ]

2 Tubes of 10 ml PLAIN RED-TOP: Serum Samples
Time Collected   Amount Collected   Centrifuged Time
[   ]   [   ] **mL**   [   ]

Biomarker Samples

Participant:

Participant ID

Visit: Baseline

Transfer Time

Volume of Serum Transferred

mL

Time Frozen

2 Tubes of 10 ml LAVENDER-TOP: Plasma Samples

Time Collected

Amount Collected

mL

Centrifuged Time

Transfer Time

Volume of Plasma Transferred

mL

Time Frozen

URINE

Time Collected

Amount Collected

mL

Transfer Time

Volume of Urine Transfered

Time Frozen

CSF

Time Collected

Amount Collected

cc

Transfer Time

Volume of CSF Transferred

cc

Time Frozen

Check if any of the following was performed:
- ☐ Lumbar Puncture Blood Patch
- ☐ Fluroscopy
- ☐ Lumbar Spine Film

Date of Blood Patch

Month   Day   Year

To request payment for a Spine Film or Fluroscopy procedure, you must complete an exception request.
NOTE: Payment will not be processed unless exception is approved AND procedure date below matches the date on the exception request.

Date of Fluoroscopy

Month   Day   Year

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

Date of Spine Film

Month   Day   Year

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

Fedex Tracking Number

27

Biomarker Samples

Participant:

Participant ID

Visit: Baseline

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:
Screening - start at 100000
Baseline - start at 200000
Month 6 - start at 300000
Month 12 - start at 400000
Month 18 - start at 500000
Month 24 - start at 600000
Month 36 - start at 700000
6 digit License Plate Number
    from ADNI Barcode Label (NOT from Covance Label) - see Procedures Manual for further clarification

Cells For Immortalization Speciman Collection

Participant: ⬚

Participant ID

Visit: Baseline

Instructions:
The whole blood sample must be received by the National Cell Repository
within 24 hrs of collection. The whole blood sample must be maintained
at room temperature and shipped by Federal Express - Priority
Overnight (Monday-Thursday) at ambient temperature.

EXCEPTION: Samples collected on Friday should be stored at room
temperature and shipped on Monday.

This form must be completed ASAP once the FedEx information is
available so that NCRAD can be notified of the shipment.

Phlebotomist Initials
⬚

Date of Blood Draw   Time of Blood Draw
⬚⬚ ⬚⬚ ⬚⬚⬚⬚   ⬚
Month Day   Year

Date Fedexed   Fedex Tracking Number
⬚⬚ ⬚⬚ ⬚⬚⬚⬚   ⬚
Month Day   Year

Volume of Blood Shipped
in 2 - 8.5cc yellow top tubes
⬚   **cc**

6 digit License Plate Number
from ADNI Barcode Label (NOT from Covance label) - see Procedures Manual for further clarification

⬚

Method of CSF Collection

Participant:

Participant ID

Visit: Baseline

Examiner Initials

Examination Date

Date must match the exam date entered on Biomarker Samples Form for the CSF collection.

Month   Day   Year

For CSF collected, please answer the following:

Needle used:
- ☐ 20g Quincke (sharp bevelled) needle
- ☐ 22g Quincke (sharp bevelled) needle
- ☐ 25g Quincke (sharp bevelled) needle
- ☐ 22g Sprotte (atraumatic) needle
- ☐ 24g Sprotte (atraumatic) needle
- ☐ 18g

Type of collection tube used
- ☐ Polypropylene
- ☐ Polystyrene

Type of tube used for shipping
- ☐ Polypropylene
- ☐ Polystyrene

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

minutes

CSF - Local Lab Results

Participant: [   ]

Participant ID

Visit: Baseline

Date of Sampling

☐☐ ☐☐ ☐☐☐☐
Month Day   Year

Time of Sample Collection

[   ] **24 hr**

Time sent to Local Lab

[   ] **24 hr**

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**

Diagnosis Summary and Diagnosis Summary – Baseline Changes Forms

Diagnosis at Screening
There are four key inclusion criteria that define the control, MCI and AD cohorts: 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 1 the table name is PDXCONV – Diagnostic Summary
    Field is DXCURREN – Current diagnosis?

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 1 the table name is PDXCONV– Diagnostic Summary
    Field DXCONV - Has there been a conversion or reversion to NL/MCI?
    Field DXCONTYP - If YES - CONVERSION, choose type
    Field DXREV - If YES - REVERSION, choose type

Documentation to show support of conversion / reversion / or No Change is through the Diagnosis Summary – Baseline Changes Worksheet / eCRF
  • ADNI 1 the table name is BLCHANGE – Diagnostic Summary-Baseline Changes

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

Diagnostic Summary

Participant: ⬚⬚⬚⬚⬚⬚⬚⬚⬚⬚⬚⬚⬚⬚

Participant ID

Visit: Month 6

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.

Date Form Completed

⬚⬚ ⬚⬚ ⬚⬚⬚⬚
Month   Day   Year

Physician Initials

⬚⬚⬚

1. Current Diagnosis
    ☐ NL
    ☐ MCI
    ☐ AD

2. Has there been a conversion or reversion to NL/MCI?
    ☐ Yes - Conversion
    ☐ Yes - Reversion
    ☐ No

    If YES - CONVERSION, choose type
        ☐ Normal Control to MCI
        ☐ Normal Control to AD
        ☐ MCI to AD

    If YES - REVERSION, choose type
        ☐ MCI to Normal Control
        ☐ AD to MCI
        ☐ AD to Normal Control

3. Physician Diagnosis
Normal
    ☐ Yes

Mild Depression
    ☐ Yes

Mild Cognitive Impairment
    ☐ Yes

    If Mild Cognitive Impairment, select any that apply:
        ☐ MCI (Memory features)
        ☐ MCI (Non-memory features)

Petersen Criteria:
        1. Subjective memory complaint
            ☐ Yes
            ☐ No

        2. Informant memory complaint
            ☐ Yes
            ☐ No

3. Normal general cognitive function
    - ☐ Yes
    - ☐ No
    - ☐ Marginal

4. Normal activities of daily living
    - ☐ Yes
    - ☐ No
    - ☐ Marginal

5. Objective memory impairment for age and education
    - ☐ Yes
    - ☐ No

6. Not demented by diagnostic criteria
    - ☐ Yes
    - ☐ No

If MCI
- ☐ MCI due to Alzheimer's Disease
- ☐ MCI due to other etiology

If MCI due to other etiology, select box(es) to indicate reason:
- ☐ Frontal Lobe Dementia
- ☐ Parkinson's Disease
- ☐ Huntington's Disease
- ☐ Progressive Supranuclear Palsy
- ☐ Corticobasal Degeneration
- ☐ Vascular Dementia
- ☐ Prion-Associated Dementia
- ☐ Other (specify)

Other (specify)

Alzheimer's Disease
- ☐ Yes

If Alzheimer's Disease, select box that indicates best description:
- ☐ Mild
- ☐ Moderate
- ☐ Severe

If Alzheimer's Disease
- ☐ Probable
- ☐ Possible

If Probable AD, select box(es) for other symptoms present:
- ☐ None
- ☐ Stroke(s)
- ☐ Depression
- ☐ Delirium
- ☐ Parkinsonism
- ☐ Metabolic/Toxic Disorder (specify)
- ☐ Other (specify)

Metabolic/Toxic Disorder (specify)

Other (specify)

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)

Atypical clinical course or features (specify)

Metabolic / Toxic Disorder (specify)

Other (specify)

Parkinsonism
☐ Yes

If Parkinsonism, select box which indicates best diagnosis:
☐ Parkinsonism without cognitive impairment
☐ Parkinsonism with cognitive impairment, not demented
☐ Parkinsonism with cognitive impairment, demented
☐ Atypical Parkinsonism

If Parkinsonism with cognitive impairment, demented
☐ PD
☐ PDD
☐ DLB
☐ PDAD

If Atypical Parkinsonism
☐ PSP
☐ CBGD
☐ OPCA
☐ SND
☐ Shy Drager
☐ Vascular
☐ Other (specify)

Other (specify)

Other Dementia (not Alzheimer's Disease)
☐ Yes

If Other Dementia, select box which indicates best diagnosis:
- ☐ Frontal
- ☐ Huntington
- ☐ Alcohol
- ☐ NPH
- ☐ Major Depression
- ☐ Down's Syndrome
- ☐ Vascular Dementia
- ☐ Prion
- ☐ HIV
- ☐ Primary Progressive Aphasia
- ☐ Posterior Cortical Dysfunction
- ☐ Other (specify)

Other (specify)

Physician Confidence in Diagnosis:
- ☐ Uncertain
- ☐ Mildly Confident
- ☐ Moderately Confident
- ☐ Highly Confident

Diagnostic Summary - Baseline Changes

Participant: [   ]

Participant ID

Visit: Month 6

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

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

1.5T MRI Scan Information

Participant: ⬚

Participant ID

Visit: Screening

To be completed by Study Coordinator (on paper only):

Site Code:_____
Study Coordinator Name:_____
Telephone #:_____
ADNI Participant Initials:_____
Anticipated Date of MRI Scan ____/____/____
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.

Important: It is mandatory that the ADNI site qualified scanner be used for all participants in the ADNI study. It is also mandatory that the same ADNI approved sequences are used at all ADNI scans.

MRI Operator Initials ⬚   Scan Date ⬚⬚⬚⬚⬚⬚⬚

Month   Day   Year

Please follow instructions in the ADNI Technical Manual for positioning the participant in the head coil. Please Stereotactic Marker on the patients (RT) temple.

1. 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

2. Straight Sagittal MPRAGE Sequence
   **Please position the acquisition box to contain the whole brain and skull. Studies without full brain coverage cannot be processed. Please review the scan for motion and other artifacts. Please re-acquire if necessary.
   MPRAGE - Completed?
   ☐ Yes
   ☐ No

Comments

3. Repeat Straight Sagittal MPRAGE Sequence
   **Repeat of Scan 2 unless a change is required to adjust for correct coverage.Repeat MPRAGE - Completed?
   ☐ Yes
   ☐ No

Comments

4. B1 Calibration Head Coil Scan (Only applicable
for phased array head coil on GE and Siemens systems)

Comments

   **Please position the acquisition box
   to contain the whole brain and skull.
   Studies without full brain coverage cannot
   be processed. Please review the scan for
   motion and other artifacts. Please re-acquire
   if necessary.
   B1 Calibration (Head) - Completed?
   ☐ Yes
   ☐ No

5. B1 Calibration Body Coil Scan (Only applicable
for phased array head coil on GE and Siemens systems)

Comments

   **Please position the acquisition box
   to contain the whole brain and skull.
   Studies without full brain coverage cannot
   be processed. Please review the scan for
   motion and other artifacts. Please re-acquire
   if necessary.
   B1 Calibration (Body) - Completed?
   ☐ Yes
   ☐ No

6. Straight Axial Fast or Turbo Spin Echo

Comments

   **Please position the acquisition stack
   to contain the whole brain from below
   cerebellum through top of head.
   Completed?
   ☐ Yes
   ☐ No

7. In new exam; Perform ADNI QC Scan. Localizer
and Straight Sagittal MPRAGE (with increased slice
thickness to ensure phantom coverage)

Comments:

   ADNI QC Scan - Completed?
   ☐ Yes
   ☐ No

8. Data Transfer and Local Data Archive:
Was data transferred to LONI within 24 hours of scan?
   Data must be transmitted to LONI within 24 hours of the MRI scan. If your site is unable to complete
   the transfer within 24 hours please indicate the problem in the "Comments" section below.
   ☐ Yes
   ☐ No

   Transfer Date

   ☐☐ ☐☐ ☐☐☐☐
   Month   Day   Year

Comments

Data Archived Locally
If No, please explain under comments.
☐ Yes
☐ No

Archive Medium   Comments

MRI Clinical Read

Participant: [   ]

Participant ID

Visit: Screening

Examiner Initials

[   ]

Examination Date

[ ] [ ] [ ] [ ] [ ] [ ]

Month   Day   Year

Upload 1.5T MRI Clinical Read:

NOTE: Only the participant number should be included on the forms being uploaded. Please remove all other patient identifiers.

No file has been uploaded.

Is the MRI compatible with the Inclusion/Exclusion Criteria?

☐ Yes

☐ No

If No, explain:

[   ]

Clinician's Signature:_____ Date:_____

3T MRI Scan Information

Participant:

[   ]

Participant ID

Visit: Baseline

To be completed by Study Coordinator:

Site Code:_____
Study Coordinator Name:_____
Telephone #:_____
ADNI Participant Initials:_____
Anticipated Date of MRI Scan ____/____/____
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

Reason why the scan was not conducted:
☐ Illness
☐ Participant unavailable
☐ Participant unwilling
☐ Administrative problems
☐ Withdrawn consent
☐ Other (specify)

If Other, specify:

[   ]

Important: It is mandatory that the ADNI site qualified scanner be used for all participants in the ADNI study. It is also mandatory that the same ADNI approved sequences are used at all ADNI scans.

MRI Operator Initials   Scan Date

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

Please follow instructions in the ADNI Technical Manual for positioning the participant in the head coil. Please Stereotactic Marker on the patients (RT) temple.

1. 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

[   ]

2. Straight Sagittal MPRAGE Sequence

Comments

   ***Please position the acquisition box
   to contain the whole brain and skull.
   Studies without full brain coverage cannot
   be processed. Please review the scan for
   motion and other artifacts. Please re-acquire
   if necessary.
   MPRAGE - Completed?*
   □ Yes
   □ No

3. Repeat Straight Sagittal MPRAGE Sequence

Comments

   ***Repeat of Scan 2 unless a change is
   required to adjust for correct coverage.Repeat
   MPRAGE - Completed?*
   □ Yes
   □ No

4. B1 Calibration Head Coil Scan (Only applicable
for phased array head coil on GE and Siemens systems)

Comments

   ***Please position the acquisition box
   to contain the whole brain and skull.
   Studies without full brain coverage cannot
   be processed. Please review the scan for
   motion and other artifacts. Please re-acquire
   if necessary.
   B1 Calibration (Head) - Completed?*
   □ Yes
   □ No

5. B1 Calibration Body Coil Scan (Only applicable
for phased array head coil on GE and Siemens systems)

Comments

   ***Please position the acquisition box
   to contain the whole brain and skull.
   Studies without full brain coverage cannot
   be processed. Please review the scan for
   motion and other artifacts. Please re-acquire
   if necessary.
   B1 Calibration (Body) - Completed?*
   □ Yes
   □ No

6. Straight Axial Fast or Turbo Spin Echo

Comments

   ***Please position the acquisition stack
   to contain the whole brain from below
   cerebellum through top of head.
   Completed?*
   □ Yes
   □ No

7. In new exam; Perform ADNI QC Scan. Localizer and Straight Sagittal MPRAGE (with increased slice thickness to ensure phantom coverage)

Comments:

> *ADNI QC Scan - Completed?*
> ☐ Yes
> ☐ No

Was data transferred to LONI within 24 hours of scan?

> *Data must be transmitted to LONI within 24 hours of the MRI scan. If your site is unable to complete*
> *the transfer within 24 hours please indicate the problem in the "Comments" section below.*
> ☐ Yes
> ☐ No
>
> Transfer Date
>
> ☐☐ ☐☐ ☐☐☐☐
> Month Day Year
>
> Comments

Data Archived Locally

> *If No, please explain under comments.*
> ☐ Yes
> ☐ No
>
> Archive Medium   Comments

9. 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
> > ☐ 6-12 hours
> > ☐ 13-24 hours
> > ☐ 25-48 hours
> > ☐ 49-72 hours
> > ☐ more than 72 hours

PET Scan Information

Participant:

[   ]

Participant ID

Visit: Baseline

NOTE: Every visit should have ORIGINAL scan data entered before
any rescan data is entered.

Was the scan conducted?
- ☐ Yes
- ☐ No

  Reason why the scan was not conducted:
  - ☐ Illness
  - ☐ Participant unavailable
  - ☐ Participant unwilling
  - ☐ Administrative problems
  - ☐ Withdrawn consent
  - ☐ Other (specify)

    If Other, specify:

    [   ]

Type of scan conducted
- ☐ Qualitative
- ☐ Quantitative

Scan Date

☐☐☐☐☐☐☐

Month   Day   Year

Technologist Initials

[   ]

Select one of the following scanner vendors and models:

GE
- ☐ check here

If GE, Scanner Model:
- ☐ Advance
- ☐ Discovery LS
- ☐ Discovery ST
- ☐ Discovery RX
- ☐ Discovery STE

Siemens/CTI
- ☐ check here

If Siemens/CTI, Scanner Model:
- ☐ ACCEL
- ☐ Biograph
- ☐ BioGraph BGO
- ☐ BioGraph HiRez
- ☐ EXACT
- ☐ HR+
- ☐ HRRT

Phillips
- ☐ check here

If Phillips, Scanner Model:
- ☐ Allegro
- ☐ Allegro-Neuro
- ☐ Gemini
- ☐ Gemini GLX
- ☐ Gemini-TF

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**

PET Scan Information

Participant: [   ]

Visit: Baseline

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 Range: 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

[   ]

Time scan started (emission)
 Enter '00' for seconds portion of the time if seconds are unavailable.
 [   ] **HH:MM:SS**

Provide an explanation if start time is not within the allowable window
 For Qualitative (target: +30 min): If Scan time is not within + 25-35 min from FDG injection time,
 please provide explanation;
 For Quantitative (target: no difference): If Scan time is not within within +/- 30 sec from FDG
 injection time, please provide explanation.

[   ]

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)
    ☐ 1 frame, 30 min (1x1800s)
    ☐ Quantitative

    If any deviations, describe:

Subject motion problems:
    ☐ Yes
    ☐ No

    If yes, describe:

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
    ☐ OSEM3D-OP
    ☐ 3D-Ramla
    ☐ 3D Back-projection
If OSEM or Ramla:
    # subsets:
        ☐ 14
        ☐ 16
        ☐ N/A
        ☐ Other

        If Other, specify

    # iterations:
        ☐ 2
        ☐ 4
        ☐ 6
        ☐ Other

        If Other, specify:

PET Scan Information

Participant:

Visit: Baseline

If Ramla, Lambda=0.016?
☐ Check here to confirm

If Back Projection, Ramp filter?
☐ Check here to confirm

If FORE/2D-OSEM, Brain Mode "ON" for PET only scanners or TRIM "ON" for PET/CT scanners?
☐ Check here to confirm

No post-process smoothing:
☐ Check here to confirm

Decay Correction
☐ Yes
☐ No

Scatter Correction:
☐ Yes
☐ No

Attenuation Correction:
☐ CT
☐ Ge-68+Segmentation
☐ Cs-137+Segmentation

SECTION IV. QUANTITATIVE SCAN DATA
** NOTE: If Qualitative scan, skip to SECTION V below.

Do the following agree to the nearest minute with the clock on
the PET scanner console?
Clock for blood sample withdrawal time
☐ Yes
☐ No

If No, provide the time difference

Clock for blood sample count time
☐ Yes
☐ No

If No, provide the time difference

Blood Sample Data
Background #1
Sample Count Time (24h)   Sample Plasma Volume Counted
                                                 Expected Value: 200

HH:MM:SS   **uL**

Sample Count Duration   Sample Count Rate

s   **cps**

Plasma Sample #1
Sample Draw Time (24h)   Sample Count Time (24h)   Sample BGL

HH:MM:SS   **HH:MM:SS**   **mg/dL**

PET Scan Information

Participant:

Participant ID

Visit: Baseline

Sample Plasma Volume Counted
Expected Value: 200

uL

Sample Count Duration

s

Sample Count Rate

cps

Plasma Sample #2
Sample Draw Time (24h)

HH:MM:SS

Sample Count Time (24h)

HH:MM:SS

Sample BGL

mg/dL

Sample Plasma Volume Counted
Expected Value: 200

uL

Sample Count Duration

s

Sample Count Rate

cps

Plasma Sample #3
Sample Draw Time (24h)

HH:MM:SS

Sample Count Time (24h)

HH:MM:SS

Sample BGL

mg/dL

Sample Plasma Volume Counted
Expected Value: 200

uL

Sample Count Duration

s

Sample Count Rate

cps

Plasma Sample #4
Sample Draw Time (24h)

HH:MM:SS

Sample Count Time (24h)

HH:MM:SS

Sample BGL

mg/dL

Sample Plasma Volume Counted
Expected Value: 200

uL

Sample Count Duration

s

Sample Count Rate

cps

Plasma Sample #5
Sample Draw Time (24h)

HH:MM:SS

Sample Count Time (24h)

HH:MM:SS

Sample BGL

mg/dL

Sample Plasma Volume Counted
Expected Value: 200

uL

Sample Count Duration

s

Sample Count Rate

cps

Background #2
Sample Count Time (24h)

HH:MM:SS

Sample Plasma Volume Counted
Expected Value = 200

uL

Sample Count Duration

s

Sample Count Rate

cps

Was the pipetted plasma volume 200 uL?
☐ Yes
☐ No

If No, denote volume used:

PET Scan Information

Participant: [ ]

Participant ID

Visit: Baseline

Was the plasma sample count time 1 minute?
- ☐ Yes
- ☐ No

If No, denote count time used

[ ]

Data Required for Cross Calibration of Well Counter to Scanner

Phantom Activity at Time of Scan

[ ] **mCi**

Phantom Volume

[ ] **cc**

Average Counts from Phantom Image ROI

[ ] **counts**

Aliquot Volume

[ ] **uL**

Aliquot Count Rate

[ ] **cps**

Blood Sample Data - Upload File

No file has been uploaded.

Blood Sample Data - Upload File

No file has been uploaded.

SECTION V. 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 within 24 hours please indicate the problem in the "Comments" section below.
- ☐ Yes
- ☐ No

Transfer Date

[ ][ ][ ][ ][ ][ ]

Month   Day   Year

Comments

[ ]

Data Archived Locally
If No, please explain under comments.
- ☐ Yes
- ☐ No

Archive Medium   Comments

[ ]   [ ]

SECTION VI. 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

Was the scan conducted?
- ☐ Yes
- ☐ No

Reason why the scan was not conducted:
- ☐ Illness
- ☐ Participant unavailable
- ☐ Participant unwilling
- ☐ Administrative problems
- ☐ Withdrawn consent
- ☐ Other (specify)

If Other, specify:

Scan Date

Month   Day   Year

Technologist Initials

Select one of the following scanner vendors and models:

GE
- ☐ check here

If GE, Scanner Model:
- ☐ Advance
- ☐ Discovery LS
- ☐ Discovery ST
- ☐ Discovery RX
- ☐ Discovery STE

Siemens/CTI
- ☐ check here

If Siemens/CTI, Scanner Model:
- ☐ ACCEL
- ☐ Biograph
- ☐ BioGraph BGO
- ☐ BioGraph HiRez
- ☐ EXACT
- ☐ HR+
- ☐ HRRT

Phillips
- ☐ check here

If Phillips, Scanner Model:
- ☐ Allegro
- ☐ Allegro-Neuro
- ☐ Gemini
- ☐ Gemini GLX
- ☐ Gemini-TF

Time of today's Scanner QC
Enter '00' for seconds portion of the time if seconds are unavailable.

HH:MM:SS

Time of PIB dose assay
Enter '00' for seconds portion of the time
if seconds are unavailable.

HH:MM:SS

PIB dose assay
to nearest 0.1 mCi

mCi

Time of residual PIB assay
Enter '00' for seconds portion of the time
if seconds are unavailable.

HH:MM:SS

Residual left in syringe
if >0.1 mCi

mCi

PIB Scan Information

Participant: [   ]

Participant ID

Visit: Baseline

Net injected dose of PIB
corrected for residual activity
to nearest 0.1 mCi
[   ]

PIB volume
[   ] **ml**

Time of PIB injection
Enter '00' for seconds portion of the time
if seconds are unavailable.
PIB injections should be at least 90 min
before a qualitative FDG and at least 120
minutes before a quantitative FDG.
[   ] **HH:MM:SS**

Time scan started (emission)
Enter '00' for seconds portion of the time if seconds are unavailable.
[   ] **HH:MM:SS**

Provide an explanation if start time is not within the allowable window
(Target: +50 min): If Scan time is not within + 45-55 min from PIB injection time, please
provide explanation.

[   ]

SECTION II. SCAN PROTOCOL INFORMATION

Any variations from protocol during PIB uptake?
☐ Yes
☐ No

If Yes, describe:
[   ]

Predefined acquisition protocol ID
[   ]

Indicate whether scan was static or dynamic:
☐ Static (1 x 20 min)
☐ Standard Dynamic (4 x 5 min)
☐ Dynamic (specify)

If dynamic indicate framing sequence:
1. No. of Frames   Duration:
[   ]   [   ] **seconds**

2. No. of Frames: Duration:
[   ]   [   ] **seconds**

3. No. of Frames: Duration:
[   ]   [   ] **seconds**

4. No. of Frames:

Duration:

seconds

5. No. of Frames:

Duration:

seconds

6. No. of Frames:

Duration:

seconds

7. No. of Frames:

Duration:

seconds

8. No. of Frames:

Duration:

seconds

9. No. of Frames:

Duration:

seconds

10. No. of Frames:

Duration:

seconds

Subject motion problems:
☐ Yes
☐ No

If yes, describe:

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
☐ OSEM3D-OP
☐ 3D-Ramla
☐ 3D Back-projection
If OSEM or Ramla:
subsets:
☐ 14
☐ 16
☐ N/A
☐ Other

PIB Scan Information

Participant:

Participant ID

Visit: Baseline

If Other, specify

\# iterations:
- ☐ 2
- ☐ 4
- ☐ 6
- ☐ Other

If Other, specify:

If Ramla, Lambda=0.016?
- ☐ Check here to confirm

If Back Projection, Ramp filter?
- ☐ Check here to confirm

If FORE/2D-OSEM, Brain Mode "ON" for PET only scanners or TRIM "ON" for PET/CT scanners?
- ☐ Check here to confirm

No post-process smoothing:
- ☐ Check here to confirm

Decay Correction
- ☐ Yes
- ☐ No

Scatter Correction:
- ☐ Yes
- ☐ No

Attenuation Correction:
- ☐ CT
- ☐ Ge-68+Segmentation
- ☐ Cs-137+Segmentation

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 within 24 hours please indicate the problem in the "Comments" section below.
- ☐ Yes
- ☐ No

Transfer Date

Month   Day   Year

Comments

Data Archived Locally
If No, please explain under comments.
- ☐ Yes
- ☐ No

Archive Medium   Comments

Center:		

Clinical Dementia Rating
Screening Visit

Scoring
See procedures manual for scoring instructions

Sum of Boxes ☐☐.☐

ADNI Subject Number	Examiner Initials	Examination Date
☐☐☐ __ S __ ☐☐☐☐	☐☐☐	☐☐ ☐☐ ☐☐☐☐
		Month Day Year

Global CDR ☐.☐

INSTRUCTIONS: Score only as decline from previous usual level due to cognitive loss, not impairment due to other factors.

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	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

Clinical Dementia Rating Worksheet

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 additonal 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., birthdate, 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? _____

Clinical Dementia Rating Worksheet

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)?

    ☐ Rarely   ☐ Sometimes   ☐ Usually   ☐ 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

Clinical Dementia Rating Worksheet

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

Clinical Dementia Rating Worksheet

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   ☐ Sometimes   ☐ Usually   ☐ Don't Know
   (Needs to be accompanied   (Shops for limited number
   on any shopping trip)   of items; buys duplicate items
                         or forgets needed items)

7. Is he/she able to independently carry out activities outside the home?
   ☐ Rarely or Never   ☐ Sometimes   ☐ Usually   ☐ Don't Know
   (Generally unable to perform   (Limited and/or routine,   (Meaningful participation
   activities without help)   e.g., superficial   in activities, e.g., voting.)
                         participation in church
                         or meetings; trips to
                         beauty parlor)

8. Is he/she taken to social functions outside a family home?   ☐ 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.

Clinical Dementia Rating Worksheet

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.

Clinical Dementia Rating Worksheet

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.

Clinical Dementia Rating Worksheet

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 something 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	☐ None correctly Repeated
	John	Brown,	42	Market Street,	Chicago	

   (Underline elements repeated correctly in each trial.)

Clinical Dementia Rating Worksheet

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   ☐ Incorrect

   _____

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 judgement)?   ☐ Correct   ☐ Incorrect

   _____

Clinical Dementia Rating Worksheet

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

	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

Geriatric Depression Scale

Participant: [   ]

Participant ID

Visit: Screening

Instructions:
Instruct the subject: "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."

Examiner Initials

[   ]

Examination Date

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

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)

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

Neuropsychiatric Inventory Q

Participant: _____

Participant ID

Visit: Baseline

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.

Examiner Initials

☐☐

Examination Date

☐☐☐☐☐☐☐☐
Month   Day   Year

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).

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).

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

Functional Assessment Questionnaire

Participant:

[   ]

Participant ID

Visit: Baseline

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.

Examiner Initials

[   ]

Examination Date

☐☐ ☐☐ ☐☐☐☐

Month   Day   Year

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, turing 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)

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

Inclusion Criteria

Participant:

Participant ID

Visit: Screening

Instructions:
If the answer to any question 1-19 is NO, the participant MAY
NOT be enrolled in the study without an exception from the Project
Director.

Refer to the Procedures Manual for instructions on requesting
an exception.

Examiner Initials

Date Criteria Confirmed

Month Day   Year

1. Have the participant and study partner signed the Informed Consent form?
    ☐ Yes
    ☐ No

    If Yes, date signed

    Month   Day   Year

    Check the following to indicate the participant is suitable for and consents to:
    ☐ 1.5 Tesla MRI
    ☐ PET Scan
    ☐ 3 Tesla MRI
    ☐ Lumbar Puncture

2. NL - Is participant free of memory complaints, verified by an informant, aside from those normal
with age?MCI - Does the subject have memory complaints and memory difficulties that are verified by
an informant?AD - Does the subject have memory complaints that are verified by an informant?
    ☐ Yes
    ☐ No

3. NL - Normal memory function documented by scoring at specific cutoffs on the Logical Memory II subscale
(delayed Paragraph Recall) from the Wechsler Memory Scaled - Revised (the maximum score is 25)MCI/AD
- Abnormal memory function documented by scoring below the educationn adjusted cutoff on the Logical
Memory II subscale (Delayed Paragraph Recall) from the Wechsler Memory Scale - Revised (the maximum
score is 25)
    ☐ Yes
    ☐ No

4. NL/MCI - Does the participant have Mini-Mental State Exam score between 24 and 30 (inclusive)? (Exceptions
must be made for subjects with less than 8 years of education at the discretion of the project director).AD
- Does the participant have an MMSE score between 20 and 26 (inclusive)?
    ☐ Yes
    ☐ No

5. NL - Does the participant have a Clinical Dementia Rating of 0? Memory Box score must be 0.MCI -
Does the participant have a Clinical Dementia Rating of 0.5? Memory Box score must be at least 0.5.AD
- Does participant have a Clinical Dementia rating of 0.5 or 1.0?
    ☐ Yes
    ☐ No

6. NL - Is the participant cognitively normal based on an absence of significant impairment in cognitive functions or activities of daily living?MCI - Is the participant's general cognition and functional performance sufficiently perserved such that a diagnosis of Alzheimer's disease cannot be made by the site physician at the time of the screening visit? AD - Does the participant meet NINCDS/ADRDA criteria for probable AD?

☐ Yes
☐ No

7. Does the participant have a Modified Hachinski score less than or equal to 4?

☐ Yes
☐ No

8. Is the participant between 55 and 90 years of age inclusive?

☐ Yes
☐ No

9. Has the participant been on stable doses of non-excluded medications for at least 4 weeks prior to screening?

☐ Yes
☐ No

10. Does the participant have a Geriatric Depression Scale score of <6?

☐ Yes
☐ No

11. Does the participant have an informant available who they have frequent contact with (e.g. an average of 10 hours per week or more), and can accompany the participant to all clinic visits and imaging sessions for the duration of the protocol?

☐ Yes
☐ No

12. Does the participant have adequate visual and auditory acuity to allow neuropsychological testing?

☐ Yes
☐ No

13. Is the participant in good general health with no additional diseases expected to interfere with the study?

☐ Yes
☐ No

14. If female, is the participant not pregnant, lactating, or of childbearing potential (i.e. women must be two years post-menopausal or surgically sterile)?

☐ Yes
☐ No
☐ N/A

15. NL/MCI - Is the participant willing and able to complete all Baseline assessment and participate in a 3-year protocol?AD - Is the participant willing and able to ...2-year protocol?

☐ Yes
☐ No

16. Is the participant willing to undergo MRI 1.5 Tesla neuroimaging (PET and MRI 3 Tesla are optional) and provide DNA for ApoE assessments and banking as well as plasma samples at protocol specified time points?

☐ Yes
☐ No

17. Has the participant completed 6 grades of education (or had a good work history sufficient to exclude mental retardation)?
- ☐ Yes
- ☐ No

18. Is the participant fluent in English or Spanish?
- ☐ Yes
- ☐ No

19. Is the participant physically acceptable for this study as confirmed by the:

19a. Medical History
- ☐ Yes
- ☐ No

19b. Physical Examination?

Must be answered "No" if any Screening Vital Signs are missing.
- ☐ Yes
- ☐ No

19c. Neurological Examination?
- ☐ Yes
- ☐ No

19d. Laboratory Tests?
- ☐ Yes
- ☐ No

Exclusion Criteria

Participant: [   ]
Participant ID

Visit: Screening

Instructions:
If the answer to any question 1-11 is YES, the participant MAY
NOT be enrolled in the study without an exception from the Project
Director.

Refer to the Procedures Manual for instructions on requesting
an exception.

Examiner Initials
[   ]

Date Criteria Confirmed
[ ][ ][ ][ ][ ][ ][ ][ ]
Month   Day   Year

1. NL - Does the participant have a significant neurologic 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.MCI - Does the participant
have a significant neurologic disease other than suspected incipient Alzheimer's disease such as...AD
- Does the participant have a significant neurologic disease other than Alzheimer's disease including...

☐ Yes
☐ No

2. Does the participant's screening/baseline MRI scans have evidence of infection, infarction, or other
focal lesions? Participants with multiple lacunes or lacunes in a critical memory structure are excluded.

This item should be left unanswered until after the Screening MRI scan has been conducted.
☐ Yes
☐ No

3. Does the participant have a pacemaker, aneurysm clips, artificial heart valves, ear implants, metal
fragments or foreign objects in the eyes, skin or body.
☐ Yes
☐ No

4. NL - Has the participant had major depression or bipolar disorder as described in DSM-IV within the
past year or a history of schizophrenia (DSM IV criteria)?MCI/AD - Does the participant have a history
of major depression...or a history of psychotic features, agitation, or behavioral problems within the
last 3 months which could lead to difficulty complying with the protocol?
☐ Yes
☐ No

5. Does the participant have a history of alcohol or substance abuse or dependence within the past 2
years (DSM IV criteria)?
☐ Yes
☐ No

6. Does the participant have a significant systemic illness or unstable medical condition which could
lead to difficulty complying with the protocol?
☐ Yes
☐ No

7. Does the participant have any clinically significant abnormalities in B12, RPR, or TFTs that might interfere with the study.
  - ☐ Yes
  - ☐ No

8. Does the participant reside in a skilled nursing facility?
  - ☐ Yes
  - ☐ No

9. Is the participant currently taking, or has he/she taken in the last 4 weeks, any excluded medication(s) as described in the Procedures Manual?
  - ☐ Yes
  - ☐ No

10. Has the participant used another investigational agent within one month prior to screening?
  - ☐ Yes
  - ☐ No

11. Is the participant participating in a clinical study involving neuropsychological measures being collected more than one time per year?
  - ☐ Yes
  - ☐ No

Eligibility Confirmation

Participant:

Participant ID

Visit: Screening

Examiner Initials

Date Eligibility Confirmed

Month   Day   Year

Status of participant at this visit (check one):

☐ Participant eligible for protocol, ready for monitor approval and randomization

☐ Participant excluded from protocol

Reason participant excluded from protocol:

Clinician's Signature:_____ Date:_____

Early Discontinuation and Withdrawal

Participant: [   ]

Participant ID

Visit: Month 24

Examiner Initials

[   ]

Date of Discontinuation/Withdrawal

[ ][ ] [ ][ ] [ ][ ][ ][ ]

Month   Day   Year

1. Is this a Full or Partial Withdrawal?
    ☐ Full
    ☐ Partial

    If Partial, what is the participant withdrawing from?
        NOTE: If the participant wishes to withdraw from in-clinic visits, Full Withdrawal should be
        completed. PIB subjects withdrawing from PET must also withdraw from PIB.
        ☐ 1.5 T MRI
        ☐ 3.0 T MRI
        ☐ PET
        ☐ Lumbar Puncture
        ☐ PIB

    Reason for Withdrawal
        ☐ Adverse Event
        ☐ Death
        ☐ Safety Risk
        ☐ Protocol Violation
        ☐ Non-Compliance
        ☐ Investigator Judgment
        ☐ Consent Withdrawn
        ☐ Study Terminated
        ☐ Loss of Study Partner
        ☐ Lost to Follow-Up
        ☐ Coordinating Center Request

    Please provide any additional information regarding the withdrawal. If individual procedures are
    being discontinued for different reasons, please provide an explanation.

    [   ]

2. Follow-up: (check all that apply)
    NOTE: If the participant agrees to an unscheduled visit, complete an exception log request.
    ☐ Agrees to return for all follow-up visits.
    ☐ Agrees to return for final visit.
    ☐ Agrees to unscheduled visit.
    ☐ Refuses/unable to return for any future visits.

Alzheimer's Disease Neuroimaging Initiative (ADNI)

Cognitive Testing

Screening Visit
Order of Assessment

1. MMSE
2. Logical Memory IA
3. Logical Memory IIA

Alzheimer's **D**isease **N**euroimaging **I**nitiative (**ADNI**)

Cognitive Testing

Baseline Visit

Order of Assessment

1. ADAS
2. Clock Drawing Test
3. Auditory Verbal Learning Test (A.V.L.T.) - Version A
4. Digit Span Forward
5. Digit Span Backward
6. Category Fluency Test
7. Trail Making Test
8. WAIS-R Digit Symbol Substitution Test
9. Boston Naming Test
10. Auditory Verbal Learning Test (A.V.L.T.) - Version A (30 Minute Delay)
11. American National Adult Reading Test

ADNI

Alzheimer's **D**isease **N**euroimaging **I**nitiative (**ADNI**)

Cognitive Testing

Month 6 Visit
Order of Assessment

1. MMSE
2. ADAS
3. Clock Drawing Test
4. Auditory Verbal Learning Test (A.V.L.T.) - Version B
5. Digit Span Forward
6. Digit Span Backward
7. Category Fluency Test
8. Trail Making Test
9. WAIS-R Digit Symbol Substitution Test
10. Boston Naming Test
11. Auditory Verbal Learning Test (A.V.L.T.) - Version B (30 Minute Delay)

Alzheimer's **D**isease **N**euroimaging **I**nitiative (**ADNI**)

Cognitive Testing

Month 12 Visit

Order of Assessment

1. MMSE
2. ADAS
3. Clock Drawing Test
4. Logical Memory IA
5. Auditory Verbal Learning Test (A.V.L.T.) - Version A
6. Digit Span Forward
7. Digit Span Backward
8. Category Fluency Test
9. Trail Making Test
10. WAIS-R Digit Symbol Substitution Test
11. Boston Naming Test
12. Logical Memory IIA
13. Auditory Verbal Learning Test (A.V.L.T.) - Version A (30 Minute Delay)

Alzheimer's **D**isease **N**euroimaging **I**nitiative (**ADNI**)

Cognitive Testing

Month 18 Visit (MCI SUBJECTS ONLY)
Order of Assessment

1. MMSE
2. ADAS
3. Clock Drawing Test
4. Auditory Verbal Learning Test (A.V.L.T.) - Version B
5. Digit Span Forward
6. Digit Span Backward
7. Category Fluency Test
8. Trail Making Test
9. WAIS-R Digit Symbol Substitution Test
10. Boston Naming Test
11. Auditory Verbal Learning Test (A.V.L.T.) - Version B (30 Minute Delay)

Alzheimer's **D**isease **N**euroimaging **I**nitiative (**ADNI**)

Cognitive Testing

Month 24 Visit

Order of Assessment

1. MMSE
2. ADAS
3. Clock Drawing Test
4. Logical Memory IA
5. Auditory Verbal Learning Test (A.V.L.T.) - Version A
6. Digit Span Forward
7. Digit Span Backward
8. Category Fluency Test
9. Trail Making Test
10. WAIS-R Digit Symbol Substitution Test
11. Boston Naming Test
12. Logical Memory IIA
13. Auditory Verbal Learning Test (A.V.L.T.) - Version A (30 Minute Delay)

Alzheimer's **D**isease **N**euroimaging **I**nitiative (**ADNI**)

Cognitive Testing

Month 36 Visit

Order of Assessment

1. MMSE
2. ADAS
3. Clock Drawing Test
4. Logical Memory IA
5. Auditory Verbal Learning Test (A.V.L.T.) - Version B
6. Digit Span Forward
7. Digit Span Backward
8. Category Fluency Test
9. Trail Making Test
10. WAIS-R Digit Symbol Substitution Test
11. Boston Naming Test
12. Logical Memory IIA
13. Auditory Verbal Learning Test (A.V.L.T.) - Version B (30 Minute Delay)

Alzheimer's Disease Neuroimaging Initiative (ADNI)

Cognitive Testing

Month 48 Visit (NL and MCI Subjects Only)
Order of Assessment

1. MMSE
2. ADAS
3. Clock Drawing Test
4. Logical Memory IA
5. Auditory Verbal Learning Test (A.V.L.T.) - Version A
6. Digit Span Forward
7. Digit Span Backward
8. Category Fluency Test
9. Trail Making Test
10. WAIS-R Digit Symbol Substitution Test
11. Boston Naming Test
12. Logical Memory IIA
13. Auditory Verbal Learning Test (A.V.L.T.) - Version A (30 Minute Delay)

Cognitive Assessment Placeholder due to Copyright Restrictions

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

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

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

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

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

ADNI Subject Number	Examiner Initials	Examination Date
☐☐☐_S_☐☐☐☐	☐☐☐	☐☐ ☐☐ ☐☐
		Month Day Year

ADAS Initial Conversation Notes

Instructions:

For specific instructions, refer to the procedures manual. The first 10 minutes are spent in open-ended conversation in order to assess various aspects of expressive and receptive speech. Then the remaining cognitive tests are administered. Language abilities are evaluated throughout the interview and on specific tests. Questions eliciting "yes" and "no" answers assess comprehension on a very basic level. Other questions should require specific information and well-developed communication skills.

Engage the subject in a short conversation about neutral topics (for example: weather, the subject's trip to the clinic, or what the subject had for breakfast). This conversation will help to put the subject at ease before the testing begins and will give the examiner an opportunity to observe how well the subject can use and understand language. There are three clinical ratings of language ability on the cognitive part of the ADAS. Use this page to record your interview notes. Documentation should be evident on this form to support rating of Spoken Language Ability (Item 10), Word Finding Difficulty (Item 11) and Comprehension (Item 12). Any rating of impairment must be supported by notes documented on this page.

Possible Topics:	Appetite	Sleep	Exercise	Other
1) Comprehension				
2) Spoken Language				
3) Word Finding				

Testing Comments: _____

_____

_____

_____

_____

ADNI Subject Number

| | | | _S_ | | | | |

---

1. **Word-recall** (Word Recall List 1)
    To begin testing, say: **"I am going to show you some words printed on these white cards. Please read each word out loud and try to remember it, because later I will ask you to try to remember all of the words I have shown you. Ready, read the word and try to remember it."**

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

Word recalled?

Trial 1	Yes
Butter	
Arm	
Shore	
Letter	
Queen	
Cabin	
Pole	
Ticket	
Grass	
Engine	

Total: ____

Word recalled?

Trial 2	Yes
Pole	
Letter	
Butter	
Queen	
Arm	
Shore	
Grass	
Cabin	
Ticket	
Engine	

Total: ____

Word recalled?

Trial 3	Yes
Shore	
Letter	
Arm	
Cabin	
Pole	
Ticket	
Engine	
Grass	
Butter	
Queen	

Total: ____

TIME ENDED: | | | | |
(24-hour clock)

ADNI Subject Number

☐☐☐_S_☐☐☐☐

2. Commands

This item is designed to assess receptive speech. The subject is asked to carry out five separate commands with 1 to 5 steps per command. Each command should be read once. If the subject does not respond or looks confused, or asks for a repetition, the examiner should give the <u>entire</u> command one more time. Then go on to the next command. All commands should be given to every subject. ***Examiner should check a response (yes/no) for every command.***

To begin testing, say: **"Now I am going to ask you to do a few things. First..."**

		Response correct?	
		Yes	**No**
a.	"Make a fist."	☐	☐
b.	"Point to the ceiling, and then to the floor."	☐	☐

Line up a pencil, watch and card (in that order) on the table.

c.	"Put the pencil on top of the card and then put it back."	☐	☐
d.	"Put the watch on the other side of the pencil and then turn over the card."	☐	☐
e.	"Tap each shoulder twice with two fingers, keeping your eyes shut."	☐	☐

3. Constructional Praxis

This test assesses the subject's ability to copy 4 geometric forms. The forms should be presented one at a time. If the subject looks confused or dissatisfied with the drawing, or asks to try again, the subject should be allowed ***a second attempt*** for each shape. If a second attempt is made, ask the subject to indicate which one is better, and score only that attempt. *Examiner should check a response (yes/no) for every form.*

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

		Drawn correctly?	
		Yes	**No**
a.	**Circle:**	☐	☐

A closed curved figure.

b.	**Two overlapping rectangles:**	☐	☐

Forms must be four-sided, and overlap must be similar to presented form.
Changes in size are not scored.

c.	**Diamond:**	☐	☐

Figure must be four-sided, oriented so that the points are at the top and bottom, and the sides approximately equal in length (e.g., longest side is not $\geq$ 1.5 times the length of the shortest side).

d.	**Cube:**	☐	☐

The form is 3-dimensional, with front face in the correct orientation, internal lines drawn correctly between corners. Opposite sides of faces should be approximately parallel.
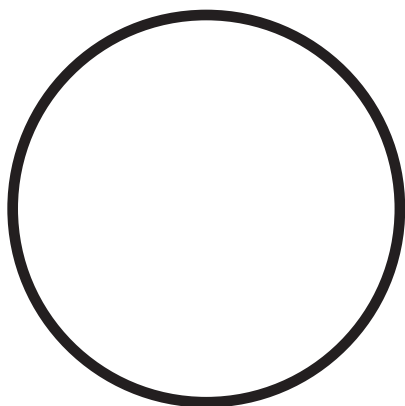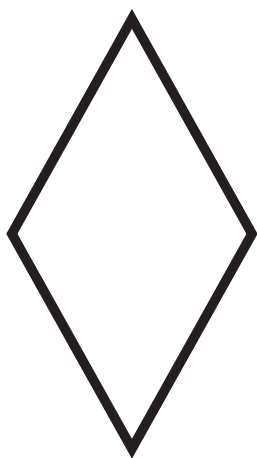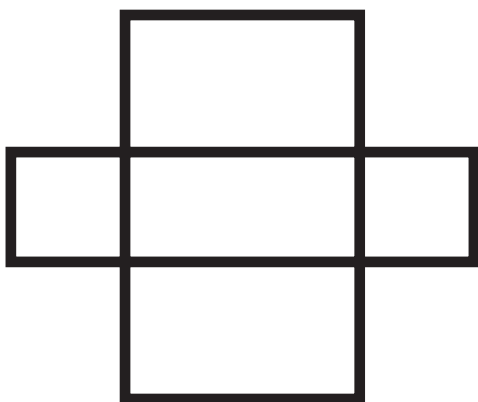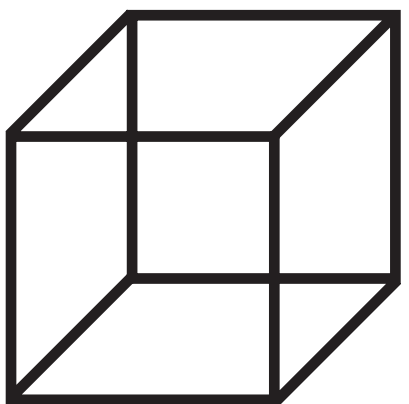
ADNI Subject Number

☐☐☐_S_☐☐☐☐

TIME BEGAN: ☐☐☐☐ (24-hour clock)

4. Delayed Word-recall task (Word Recall List 1)

Ask the subject to recall as many words as possible from the words presented in the Immediate Word Recall task.

To begin testing, say: **"A few minutes ago I had you read some words printed on these cards.** (point to word list) **Tell me all of the words you can remember that were on the cards."** Prompt with **"Any others?"** as necessary. Discontinue if no response or if the subject indicates he/she cannot recall any more after prompting. *Examiner should check "yes" for every word recalled correctly.*

	Word recalled?
	Yes
Butter	
Arm	
Shore	
Letter	
Queen	
Cabin	
Pole	
Ticket	
Grass	
Engine	

Total: ☐

ADNI Subject Number

□ □ □ _S_ □ □ □ □

5. **Naming Objects / Fingers**

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

Response correct?

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

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

Response correct?

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

ADNI Subject Number

☐☐☐ _S_ ☐☐☐☐

6. Ideational Praxis

This item is designed to determine whether the subject can perform a familiar but complex sequence of actions. There are 5 tasks to this item. Place a long envelope, an 8½″ × 11″ sheet of paper and a pencil in front of the subject.

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

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

Task	Action correct?	
	Yes	**No**
a. Fold the paper	☐	☐
b. Put the paper in the envelope	☐	☐
c. Seal the envelope	☐	☐
d. Address the envelope to yourself	☐	☐
e. Show me where the stamp goes	☐	☐

7. Orientation

This item is designed to determine how well oriented the subject is with regard to time and place. Ask the subject for each of these pieces of information **one at a time**. One restatement of each question is allowed (*e.g.*, if subject confuses day and date.) *Examiner should check a response (yes/no) for every question.*

	Response correct?	
	Yes	**No**
a. Full name (must be exact)	☐	☐
b. Month (must be exact)	☐	☐
c. Date (± 1 day)	☐	☐
d. Year (must be exact)	☐	☐
e. Day of the week (must be exact)	☐	☐
f. Season (within 1 week of upcoming season or within 2 weeks of previous season)	☐	☐
g. Place (partial names are acceptable, but generic terms are not) (Say: **"Where are we now?"** or **"What is the name of this place?"**)	☐	☐
h. Clock Time (± 1 hour) (Say: **"Without looking at your watch, tell me approximately what time it is."**)	☐	☐

ADNI Subject Number

☐☐☐_S_☐☐☐☐

Check subject response

8. **Word Recognition** (List 1)
In the learning portion of this test, the subject is given one trial to learn a list of 12 words. (See procedures manual for instructions on using the stimulus cards.) Say: **"I am going to show you some words printed on these white cards. I want you to read each word out loud and try to remember it."**

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

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

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

Word	Yes	No	*R
Nurse	▓		▓
Magazine		▓	▓
Wizard		▓	
Van		▓	
Leopard		▓	
Sale	▓		
Sea		▓	
Train		▓	
Coin		▓	
Ship	▓		
Institution		▓	
Map	▓		
Axe	▓		
Board		▓	
Carrot	▓		
Milk	▓		
Volume	▓		
Forest	▓		
Anchor		▓	
Gem		▓	
Cat	▓		
Fund		▓	
Edge	▓		
Cake	▓		

*R = Reminder given

ADNI Subject Number

☐☐☐_S_☐☐☐☐

9. Remembering Test Instructions (based **only** on observations during Word Recognition task): This item evaluates the subject's ability to remember the requirements of the **Word Recognition task**. The number of reminders given on the Word Recognition task are counted to rate this item. If the Word Recognition task was not completed or not attempted, then this item must not be scored. Each instance of memory failure for the test instructions after the first two items is scored.

☐ **None** - subject never needs extra reminders of instructions

☐ **Very mild** - forgets once

☐ **Mild** - must be reminded 2 times

☐ **Moderate** - must be reminded 3 or 4 times

☐ **Moderately severe** - must be reminded 5 or 6 times

☐ **Severe** - must be reminded 7 or more times

10. Comprehension: This item evaluates the subject's ability to understand speech. To rate this item the examiner should consider how well the subject was able to understand the examiner's speech during the opening discussion and during the test session. ***Do not include responses to commands.***

☐ **None** - no evidence of poor comprehension

☐ **Very mild** - one or two instances of misunderstanding

☐ **Mild** - 3-5 instances of misunderstanding

☐ **Moderate** - requires several repetitions and rephrasing

☐ **Moderately severe** - subject only occasionally responds correctly; *i.e.*, yes/no questions

☐ **Severe** - subject rarely responds to questions appropriately, not due to poverty of speech

11. Word Finding Difficulty: To rate this item, the examiner must determine whether the subject has difficulty in finding the desired word in spontaneous speech during the interview and test session. ***Do not include finger and object naming in this rating.*** Documentation should be evident on Page 1 to support any rating above zero. (Refer to the procedures manual for guidelines)

☐ **None** - no evidence of word finding difficulty in spontaneous speech

☐ **Very mild** - 1 or 2 instances, not clinically significant

☐ **Mild** - noticeable circumlocution or synonym substitution

☐ **Moderate** - loss of words without compensation on occasion

☐ **Moderately severe** - frequent loss of words without compensation

☐ **Severe** - nearly total loss of content of words; speech sounds empty; 1-2 word utterances

Modified 6/5/06

ADNI Subject Number

☐☐☐ _S_ ☐☐☐☐

12. **Spoken Language Ability:** This item is a global rating of the quality of speech, *i.e.*, clarity, difficulty in making oneself understood. In rating this item the examiner should consider all of the speech produced by the subject in the initial interview and the test session. Documentation should be evident on Page 1 to support any rating above zero. (Refer to the procedures manual for guidelines)

☐ **None** - no instances where it is difficult to understand the subject

☐ **Very mild** - one instance of lack of understandability

☐ **Mild** - subject has difficulty less than 25% of the time

☐ **Moderate** - subject has difficulty 25-50% of the time

☐ **Moderately severe** - subject has difficulty 50% of the time

☐ **Severe** - one or two word utterance; fluent, but empty speech; mute

13. **Number Cancellation**

Instructions for Example:

Place the practice form face up in front of the subject. Say, **"On the top of this page are two numbers. Throughout this page you will find these numbers mixed in with other numbers. I'd like you to begin here..."** *(point to the beginning of the first line)* **"...and going across line by line, cross off each number that matches either of the two numbers at the top of the page. Please work as quickly as you can."** Discontinue the example after **30** seconds.

Instructions for Task:

Place the form face up in front of the subject and say: "**On the top of this page are two numbers. Throughout this page you will find these numbers mixed in with other numbers. I'd like you to begin here...**" *(point to the beginning of the first line)*, "**...and going across line by line, cross off the numbers that match the numbers at the top of the page. Please work as quickly as you can.**"

If the first cancellation done by the subject is incorrect, say: "**These are the correct numbers to cross out,**" and point to the target numbers at the top of the page. If the subject becomes confused or stops while doing the test, repeat the standard instructions as needed. Discontinue the test after **45** seconds.

☐☐ **13a.** Number Cancellation: Number of targets hit

☐☐ **13b.** Number Cancellation: Number of errors

☐☐ **13c.** Number Cancellation: Number of times reminded of task

Modified 6/5/06

"6" and "1"

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

Example for use with versions A, B, and C

"2" and "8"

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

A

Clock Drawing Test
Baseline Visit

ADNI Subject Number	Examiner Initials	Examination Date
☐☐☐_S_☐☐☐☐	☐☐☐	☐☐ ☐☐ ☐☐
		Month Day Year

1. Clock Drawing

Instructions:

Hand the subject a blank piece of paper and a pencil. Say to the subject: **"Draw the face of a clock showing the numbers and the two hands, set to ten after eleven."** If the subject is confused or asks for another try, allow the subject two attempts to complete the task. If a second attempt is done, ask the subject to indicate which one is better and score only that attempt. If requested, the examiner may remind the subject of the specific time to be shown on the clock face (see procedures manual for examples of correctly scored clock drawings).

Scoring:

Correct	Incorrect		
☐	☐	1.	Approximately circular face
☐	☐	2.	Symmetry of number placement
☐	☐	3.	Correctness of numbers
☐	☐	4.	Presence of the two hands
☐	☐	5.	Presence of the two hands, set to ten after eleven

☐ **Total Correct** (Range = 0-5)
Count the number of **CORRECT** responses.

2. Clock Copying

Instructions:

Immediately after the Clock drawing command condition is completed, present the subject with the response form with the model clock drawn at the top and say, **"Copy this clock..."** *(point to the model)* **"...in the space provided below."** Allow the subject to work without feedback; interrupt only if the subject starts to scratch out or destroy any of their drawing. If the subject tries to erase or scratch out an error, immediately intervene and gently instruct them to try again. Allow only two attempts on the Clock Copying test (see procedures manual for further instructions on scoring).

Scoring:

Correct	Incorrect		
☐	☐	1.	Approximately circular face
☐	☐	2.	Symmetry of number placement
☐	☐	3.	Correctness of numbers
☐	☐	4.	Presence of the two hands
☐	☐	5.	Presence of the two hands, set to ten after eleven

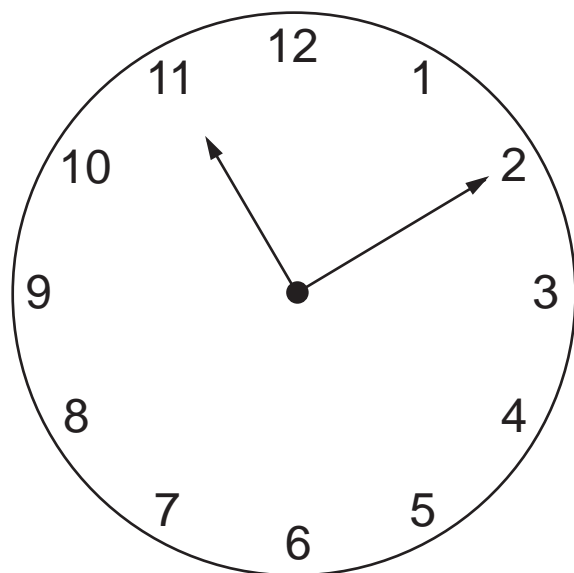☐ **Total Correct** (Range = 0-5)
Count the number of **CORRECT** responses.

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

Baseline Visit

ADNI Subject Number

☐☐☐_S_☐☐☐☐

START TIME: ☐☐☐☐
(24-hour clock)

Trial 1 Instruction:

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

Trial 2-5 Instructions:

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

List B Instructions:

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

Trial 6 Instructions:

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

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

12

Category Fluency Test
Baseline Visit

ADNI Subject Number

☐☐☐ _S_ ☐☐☐☐

Task Instructions:

Say, **"I am going to give you a category and I want you to name, as fast as you can, all of the things that belong in that category. For example, if I say 'articles of clothing,' you could say, 'shirt', 'tie', or 'hat'. Can you think of other articles of clothing?"**

Allow up to 20 seconds for the subject to produce two responses. On the below table, check the responses and read the associated instruction.

Response	Instruction
☐ No response	**" You could have said 'shoes' or 'coat' since they are articles of clothing."**
☐ One or more incorrect responses, no correct response.	**" No, _____ is (are) not an article of clothing. You could have said 'shoes' or 'coat' since they are articles of clothing."**
☐ One or more correct responses, no incorrect responses.	**" That's right. You could also have said 'shoes' or 'coat'."**
☐ One or more correct responses, one or more incorrect responses.	**" _____ is (are) correct, but _____ is (are) not an article of clothing. You also could have said 'shoes' or 'coat'."**
☐ Two or more correct responses.	**" That's right."**

PROCEED TO 'ANIMAL' AND 'VEGETABLE' CATEGORY WORK SHEETS

ADNI Subject Number

☐☐☐ _S_ ☐☐☐☐

Animal Category:

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

➲ Start timer as you say 'Begin'. Write actual responses as legibly as possible.

➲ Stop the procedure at 60 seconds.

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

Animal Total: _____

Perseverations: _____

Intrusions: _____

Baseline Visit

ADNI Subject Number

☐☐☐ _S_ ☐☐☐☐

Vegetable Category:

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

➲ Start timer as you say 'Begin'. Write actual responses as legibly as possible.

➲ Stop the procedure at 60 seconds.

1. _____
2. _____
3. _____
4. _____
5. _____
6. _____
7. _____
8. _____
9. _____
10. _____
11. _____
12. _____
13. _____
14. _____
15. _____
16. _____
17. _____
18. _____
19. _____
20. _____

21. _____
22. _____
23. _____
24. _____
25. _____
26. _____
27. _____
28. _____
29. _____
30. _____
31. _____
32. _____
33. _____
34. _____
35. _____
36. _____
37. _____
38. _____
39. _____
40. _____

41. _____
42. _____
43. _____
44. _____
45. _____
46. _____
47. _____
48. _____
49. _____
50. _____
51. _____
52. _____
53. _____
54. _____
55. _____
56. _____
57. _____
58. _____
59. _____
60. _____

Vegetable Total: _____

Perseverations: _____

Intrusions: _____

Trail Making Test
Baseline Visit

ADNI Subject Number

☐☐☐_S_☐☐☐☐

Part A Instructions: Place the Part A sample form in front of the subject. Read aloud the instructions.

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

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

If the subject completes the sample correctly, got to test A. Repeat the instructions given for the sample. Start timing as soon as the instruction is given to begin.

➲ Stop timing when Trail is completed or stop subject when maximum time is reached.

➲ Allow 150 seconds for the test.

Scoring: **Part A time to complete:** _____

Part A errors of Comission: _____

Part A errors of Omission: _____

Part B Instructions: Place the Part B sample form in front of the subject. Read aloud the instructions.

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

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

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

➲ Stop timing when Trail is completed or stop subject when maximum time is reached.

➲ Allow 300 seconds for the test.

Scoring: **Part B time to complete:** _____

Part B errors of Comission: _____

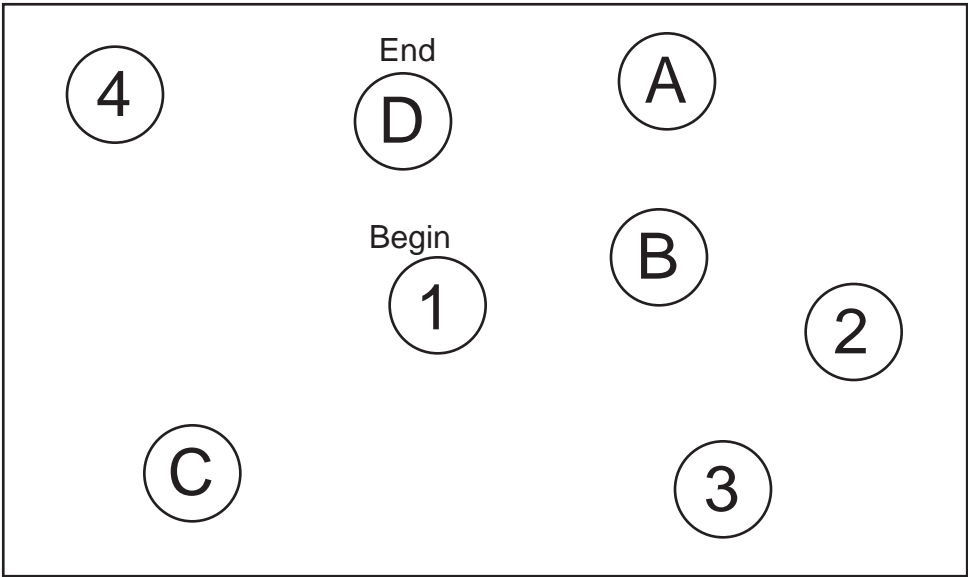**Part B errors of Omission:** _____

TRAIL MAKING

PART A

SAMPLE

15

17

21

20

19

16

18

4

22

5

13

6

Begin

1

24

7

14

2

8

10

3

9

End

11

25

23

12
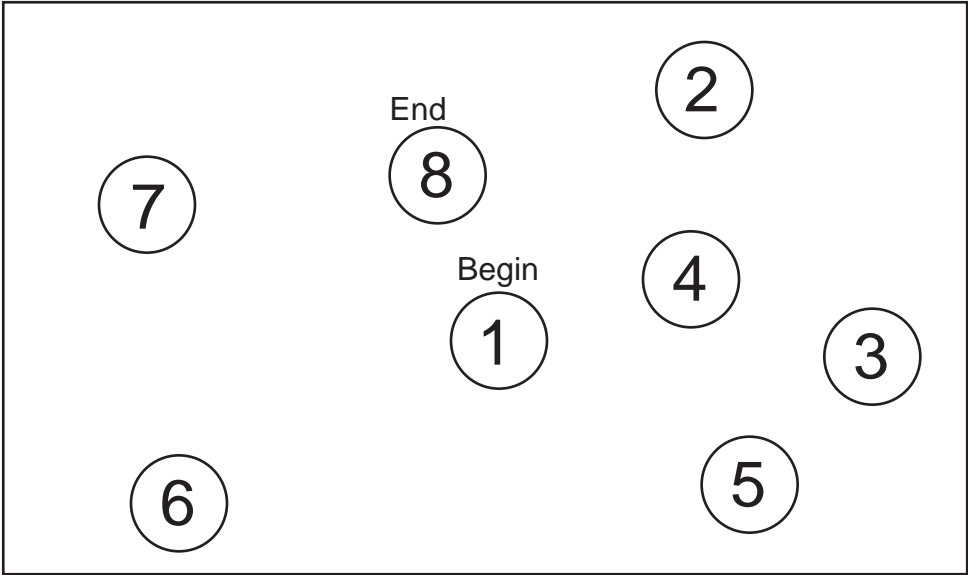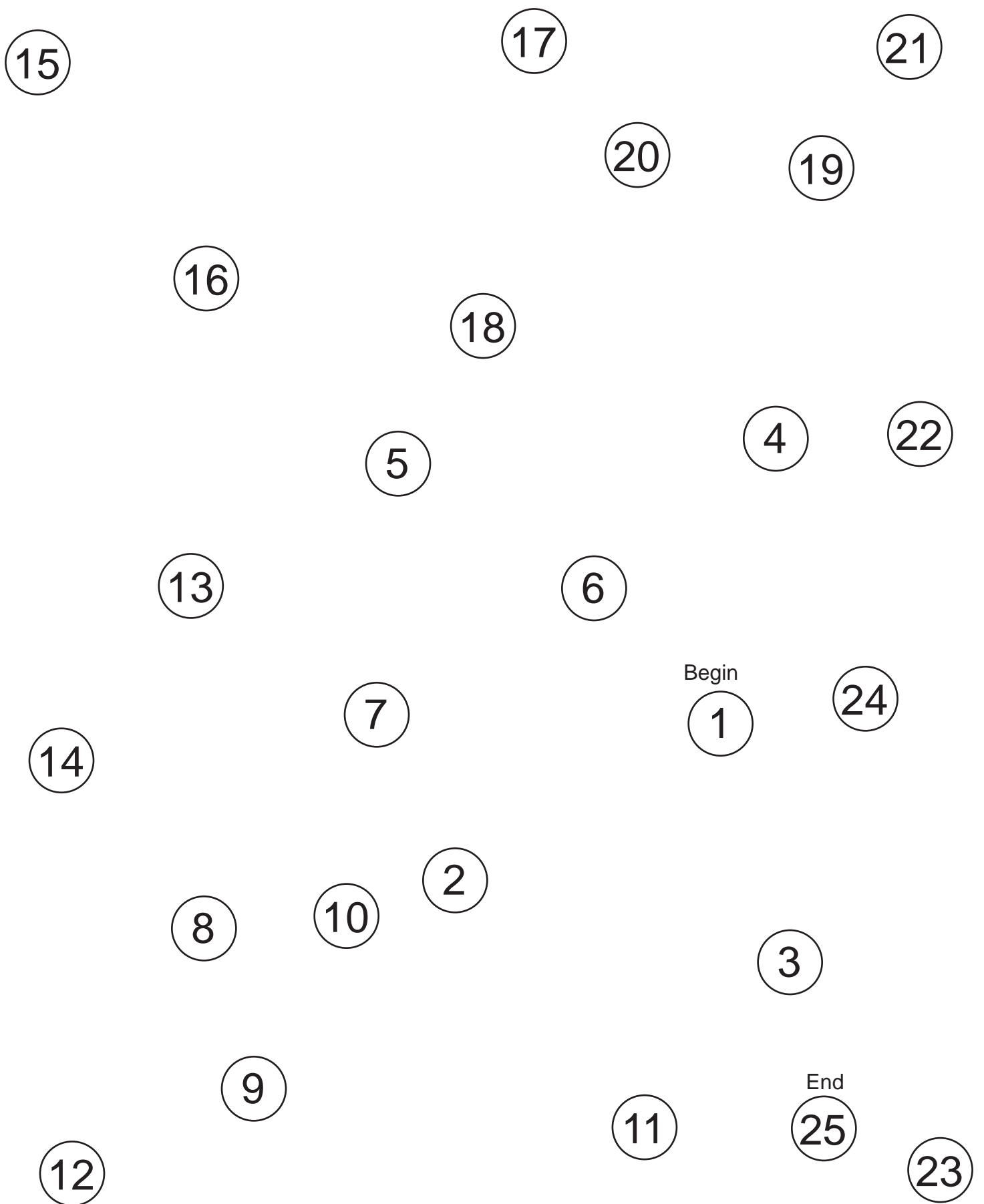
TRAIL MAKING

PART B

SAMPLE

End

13

10

8

9

I

D

4

B

3

Begin

7

1

5

H

C

12

G

A

J

2

6

L

E

F

K

11
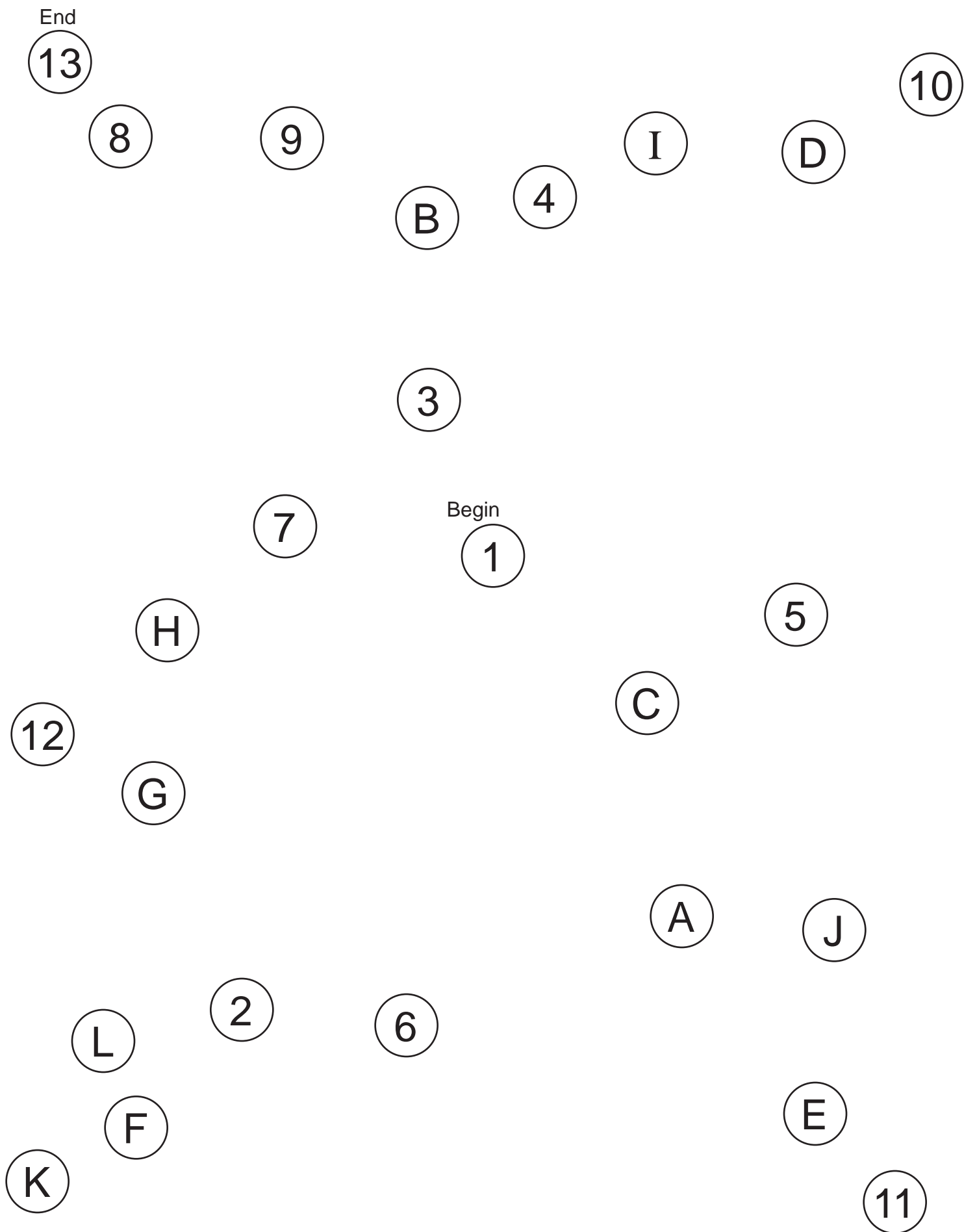
Auditory Verbal Learning Test (A.V.L.T.) Version A-30 Minute Delay

Baseline Visit

ADNI Subject Number

☐☐☐_S_☐☐☐☐

DELAY TIME: ☐☐☐☐
(24-hour clock)

30 Minute Delay Instructions:

Say, **"Awhile ago I read a list of words to you several times, and you had to repeat back the words. Tell me the words from that list."**

IMPORTANT: The words from the original list are _NOT_ read again before recall is elicited on this trial

List A (DO NOT READ)	30 MINUTE DELAY
Drum	
Curtain	
Bell	
Coffee	
School	
Parent	
Moon	
Garden	
Hat	
Farmer	
Nose	
Turkey	
Color	
House	
River	
Totals	
Intrusions	

Recognition Instructions:

Say, **"Sometimes people can remember more of the words if they see them. Read all these words and circle the ones that you think were on that first list I read...the list I read 5 times to you."**

LIST SCORES: **Recognition:** _____ **Total Intrusions:** _____

Teacher	Coffee
River	Road
Bridge	Hat
Farmer	Turkey
Pen	Minute
Forehead	Nose
Kerchief	School
House	Bell
Moon	Face
Color	Garden
Beet	Classroom
Curtain	Parent
Floor	Children
Soldier	Broomstick
Drum	Gun

Baseline Visit

ADNI Subject Number

☐☐☐_S_☐☐☐☐

Instructions: Present the subject with the word list (not the tester's worksheet) and say, **"I would like you to read a list of words aloud. Some of the words may be unfamiliar and difficult to pronounce, but do the best you can to pronounce them."**

CORRECT	INCORRECT			
☐	☐	1.	ache	**ĀK**
☐	☐	2.	debt	**DET**
☐	☐	3.	pint	**PĪNT**
☐	☐	4.	depot	**DĒ** po
☐	☐	5.	chord	**KORD**
☐	☐	6.	bouquet	bō **KĀ** ; bü **KĀ**
☐	☐	7.	deny	di **NĪ**
☐	☐	8.	capon	**KĀ** pon
☐	☐	9.	heir	**ÂR**
☐	☐	10.	aisle	**ĪL**
☐	☐	11.	subtle	**SU** tl
☐	☐	12.	nausea	**NÔ** zē ə ; **NO** sēə ; **NO** shə
☐	☐	13.	gauge	**GĀJ**
☐	☐	14.	naive	nä **ĒV**
☐	☐	15.	thyme	**TĪM**
☐	☐	16.	courteous	**KəR** tē əs
☐	☐	17.	algae	**AL** jē
☐	☐	18.	fetal	**FĒ** tl
☐	☐	19.	quadruped	**KWOD** roo ped ; **KWOD** rə ped
☐	☐	20.	epitome	i **PIT** ə mē ; ə **PID** ə mē
☐	☐	21.	superfluous	soo **PəR** floo əs ; sü **PəR** floo əs
☐	☐	22.	chamois	**SHA** mē
☐	☐	23.	papyrus	pə **PĪ** rəs
☐	☐	24.	asthma	**AZ** mə
☐	☐	25.	hiatus	hī **Ā** təs

Number of errors (1-25): _____

American National Adult Reading Test (Page 2 of 2)
Baseline Visit

ADNI Subject Number

☐☐☐_S_☐☐☐☐

CORRECT	INCORRECT			
☐	☐	26.	simile	**SI** mə lē
☐	☐	27.	blatant	**BLĀ** tənt
☐	☐	28.	cellist	**CHE** list
☐	☐	29.	zealot	**ZE** lət
☐	☐	30.	abstemious	ab **STĒ** me əs
☐	☐	31.	meringue	mə **RANG**
☐	☐	32.	placebo	plə **SĒ** bō
☐	☐	33.	facade	fə **SAD**
☐	☐	34.	pugilist	**PYOO** jə list
☐	☐	35.	virulent	**VIR** yə lənt ; **VIR** ə lənt
☐	☐	36.	worsted	**WOOS** tid ; **WəR** stid
☐	☐	37.	detente	**dā** **TANT**
☐	☐	38.	anise	**AN** is
☐	☐	39.	sieve	**SIV**
☐	☐	40.	chassis	**SHA** sē ; **CHA** sē
☐	☐	41.	beatify	bē **AT** ə fī
☐	☐	42.	scion	**SI** ən
☐	☐	43.	cabal	kə **BAL**
☐	☐	44.	apropos	a prə **PŌ**
☐	☐	45.	caprice	kə **PRĒS**
☐	☐	46.	demesne	di **MĀN** ; di **MĒN**
☐	☐	47.	imbroglio	im **BRŌL** yō
☐	☐	48.	hyperbole	hī **PəR** bə lē
☐	☐	49.	syncope	**SIN** kə pē ; **SING** kə pē
☐	☐	50.	prelate	**PREL** it ; **PREL** ət

Number of errors (26-50): _____

Total number of errors: _____

ache	gauge
debt	naive
pint	thyme
depot	courteous
chord	algae
bouquet	fetal
deny	quadruped
capon	epitome
heir	superfluous
aisle	chamois
subtle	papyrus
nausea	asthma

hiatus	anise
simile	sieve
blatant	chassis
cellist	beatify
zealot	scion
abstemious	cabal
meringue	apropos
placebo	caprice
facade	demesne
pugilist	imbroglio
virulent	hyperbole
worsted	syncope
detente	prelate