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

[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 (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]

ADNI - Execution Phase (ADNI)

Registry

Participant: _____

Participant ID

Visit: Screening

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

_____

ADNI - Execution Phase (ADNI)

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

Participant Demographic Information

Participant: _____
Participant ID

Visit: Screening

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

ADNI - Execution Phase (ADNI)

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
- ☐ Yes
- ☐ No

Alzheimer's Disease
- ☐ Yes
- ☐ No

2. Father

Dementia
- ☐ Yes
- ☐ No

Alzheimer's Disease
- ☐ Yes
- ☐ No

3. Does the participant have any siblings?

If yes, please provide additional information by clicking "Details" below.
- ☐ Yes
- ☐ No

Details

ADNI - Execution Phase (ADNI)

Family History Questionnaire Subtable

Participant: ☐☐☐☐

Participant ID

Visit: Screening

Examiner Initials

☐☐

Examination Date

☐☐☐☐☐☐☐☐

Month Day Year

Sibling

Gender

- ☐ Male
- ☐ Female

Dementia

- ☐ Yes
- ☐ No

Alzheimer's Disease

- ☐ Yes
- ☐ No

ADNI - Execution Phase (ADNI)

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

Check box corresponding to visit of last update:

Visits ☐ SC ☐ BL ☐ MO6 ☐ M12 ☐ M18 ☐ M24 ☐ M30 ☐ M36 ☐ M42 ☐ M48

ADNI Subject Number ☐☐☐_S_☐☐☐☐

Examiner Initials ☐☐☐

Examination Date ☐☐ Month ☐☐ Day ☐☐ Year

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 _____

ADNI - Execution Phase (ADNI)

Physical Exam

Participant: ☐☐☐☐☐☐☐☐☐☐

Participant ID

Visit: Screening

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.)* ☐

ADNI - Execution Phase (ADNI)

Physical Exam

Participant: _____

Participant ID

Visit: Screening

12. Other
    - ☐ Normal
    - ☐ Abnormal

    Details

    (Must be provided if 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:_____

ADNI - Execution Phase (ADNI)

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.)*

ADNI - Execution Phase (ADNI)

Neurological Exam

Participant: _____

Participant ID

Visit: Screening

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.

ADNI - Execution Phase (ADNI)

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

Baseline Symptoms Checklist

Participant: _____
Participant ID

Visit: Baseline

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

Baseline Symptoms Checklist

Participant: _____
Participant ID

Visit: Baseline

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:

Documentation of Baseline Diagnoses and Symptoms Log

Check box corresponding to visit of last update:

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

ADNI Subject Number ☐☐☐_S_☐☐☐☐

Examiner Initials ☐☐☐

Examination Date ☐☐ ☐☐ ☐☐ (Month Day Year)

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:

ADNI - Execution Phase (ADNI)

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

Diagnosis and Symptoms Checklist

Participant: _____
Participant ID

Visit: Month 12

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

Diagnosis and Symptoms Checklist

Participant: _____
Participant ID

Visit: Month 12

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

ADNI - Execution Phase (ADNI)

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

ADNI - Execution Phase (ADNI)

Adverse Events/Hospitalizations - Log

Participant: _____
Participant ID

Visit: Screening

Severity
- ☐ Mild
- ☐ Moderate
- ☐ Severe

Serious?

If Yes, complete this form to the best of your 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

Check here if:
- ☐ SAE prior to Baseline Visit

Serious Adverse Event Reported By:

Reason for Qualifying as Serious Adverse Event:

Life-Threatening?

If Yes, Serious must also be answered Yes.
- ☐ Yes
- ☐ No

Related to Imaging Procedure
- ☐ Definitely
- ☐ Possibly
- ☐ Not Related

Related to Lumbar Puncture
- ☐ Definitely
- ☐ Possibly
- ☐ Not Related

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

ADNI - Execution Phase (ADNI)

Adverse Events/Hospitalizations - Log

Participant: _____
Participant ID

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:_____

ADNI - Execution Phase (ADNI)

Modified Hachinski

Participant: ☐

Participant ID

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:_____

ADNI - Execution Phase (ADNI)

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

☐☐☐☐☐☐☐☐

Month Day Year

Time of Blood Draw

☐☐☐☐

Date Fedexed

For UPENN sites, please provide the date delivered.

☐☐☐☐☐☐☐☐

Month Day Year

Fedex Tracking Number

☐☐☐☐☐☐☐☐☐☐

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

☐☐☐☐☐☐

ADNI - Execution Phase (ADNI)

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 ☐☐☐☐☐☐☐☐ Month Day Year

Time of Collection ☐☐☐☐

Phlebotomist Initials ☐☐☐

CSF Collector Initials ☐☐☐

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

Time Collected ☐☐☐☐

Amount Collected ☐☐ **mL**

Centrifuged Time ☐☐☐☐

ADNI - Execution Phase (ADNI)

Biomarker Samples

Participant: _____
Participant ID

Visit: Baseline

Transfer Time | Volume of Serum Transferred | Time Frozen

mL

2 Tubes of 10 ml LAVENDER-TOP: Plasma Samples

Time Collected | Amount Collected | Centrifuged Time

mL

Transfer Time | Volume of Plasma Transferred | Time Frozen

mL

URINE

Time Collected | Amount Collected | Transfer Time

mL

Volume of Urine Transfered | Time Frozen

CSF

Time Collected | Amount Collected | Transfer Time

cc

Volume of CSF Transferred | Time Frozen

cc

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

ADNI - Execution Phase (ADNI)

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

☐

ADNI - Execution Phase (ADNI)

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

☐☐☐☐☐☐☐☐

Month Day Year

Time of Blood Draw

☐

Date Fedexed

☐☐☐☐☐☐☐☐

Month Day Year

Fedex Tracking Number

☐

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

☐

ADNI - Execution Phase (ADNI)

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**

ADNI - Execution Phase (ADNI)

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.

ADNI - Execution Phase (ADNI)

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

ADNI - Execution Phase (ADNI)

Diagnostic Summary

Participant: _____

Participant ID

Visit: Month 6

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

ADNI - Execution Phase (ADNI)

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

ADNI - Execution Phase (ADNI)

Diagnostic Summary - Baseline Changes

Participant: _____

Participant ID

Visit: Month 6

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

    _____

ADNI - Execution Phase (ADNI)

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

ADNI - Execution Phase (ADNI)

1.5T MRI Scan Information

Participant: _____

Participant ID

Visit: Screening

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

***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

Comments

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

***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

Comments

6. Straight Axial Fast or Turbo Spin Echo

***Please position the acquisition stack to contain the whole brain from below cerebellum through top of head.*

Completed?

☐ Yes
☐ No

Comments

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

ADNI QC Scan - Completed?

☐ Yes
☐ No

Comments:

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

ADNI - Execution Phase (ADNI)

1.5T MRI Scan Information

Participant: _____

Participant ID

Visit: Screening

Comments

_____

Data Archived Locally

If No, please explain under comments.

☐ Yes

☐ No

Archive Medium _____ Comments _____

ADNI - Execution Phase (ADNI)

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:_____

ADNI - Execution Phase (ADNI)

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

ADNI - Execution Phase (ADNI)

3T MRI Scan Information

Participant: _____

Participant ID

Visit: Baseline

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)

***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

Comments

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

***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

Comments

6. Straight Axial Fast or Turbo Spin Echo

***Please position the acquisition stack to contain the whole brain from below cerebellum through top of head.*

Completed?

☐ Yes

☐ No

Comments

ADNI - Execution Phase (ADNI)

3T MRI Scan Information

Participant: _____
Participant ID

Visit: Baseline

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

ADNI - Execution Phase (ADNI)

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**

ADNI - Execution Phase (ADNI)

PET Scan Information

Participant: _____

Participant ID

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

PET Scan Information

Participant: _____
Participant ID

Visit: Baseline

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: _____
Participant ID

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): _____ **HH:MM:SS**

Sample Plasma Volume Counted
Expected Value: 200
_____ **uL**

Sample Count Duration: _____ **s**

Sample Count Rate: _____ **cps**

Plasma Sample #1

Sample Draw Time (24h): _____ **HH:MM:SS**

Sample Count Time (24h): _____ **HH:MM:SS**

Sample BGL: _____ **mg/dL**

ADNI - Execution Phase (ADNI)

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:

_____

ADNI - Execution Phase (ADNI)

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

ADNI - Execution Phase (ADNI)

PIB Scan Information

Participant: ____________ (Participant ID)

Visit: Baseline

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**

ADNI - Execution Phase (ADNI)

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**

PIB Scan Information

Participant: _____
Participant ID

Visit: Baseline

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

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

ADNI Subject Number ___ S ___

Examiner Initials

Examination Date (Month / Day / Year)

Scoring

See procedures manual for scoring instructions

Sum of Boxes ___.___

Global CDR ___.___

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

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

ADNI Subject Number: _____

Visit: _____

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? _____

ADNI Subject Number: _____

Visit: _____

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

ADNI Subject Number: _____

Visit: _____

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

ADNI Subject Number: _____

Visit: _____

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

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

8. Is he/she taken to social functions outside a family home? ☐ Yes ☐ No
   If no, why not? _____

9. Would a casual observer of the subject's behavior think the subject was ill? ☐ Yes ☐ No

10. If in nursing home, does he/she participate well in social functions (thinking)? ☐ Yes ☐ No

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

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

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

ADNI Subject Number: _____

Visit: _____

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.

ADNI Subject Number: _____

Visit: _____

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.

ADNI Subject Number: _____

Visit: _____

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.)

ADNI Subject Number: _____

Visit: _____

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

   _____

ADNI Subject Number: _____

Visit: _____

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		
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)

ADNI - Execution Phase (ADNI)

Geriatric Depression Scale

Participant: _____

Participant ID

Visit: Screening

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

ADNI - Execution Phase (ADNI)

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).

ADNI - Execution Phase (ADNI)

Neuropsychiatric Inventory Q

Participant: _____

Participant ID

Visit: Baseline

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

ADNI - Execution Phase (ADNI)

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)

Functional Assessment Questionnaire

Participant: _____
Participant ID

Visit: Baseline

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

ADNI - Execution Phase (ADNI)

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

Inclusion Criteria

Participant: _____
Participant ID

Visit: Screening

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

Inclusion Criteria

Participant: _____
Participant ID

Visit: Screening

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

ADNI - Execution Phase (ADNI)

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

ADNI - Execution Phase (ADNI)

Exclusion Criteria

Participant: _____

Participant ID

Visit: Screening

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

ADNI - Execution Phase (ADNI)

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:_____

ADNI - Execution Phase (ADNI)

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.