ADNI Administrative Issues

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ADNI Administrative Issues

- ADNI Study Design
- ADNI Procedures
- Inclusion/Exclusion Issues
- Startup Requirements
- Subject Enrollment
- Online Database
ADNI Study Design

- Non-randomized natural history
- Non-treatment study
- 800 subjects: 200 normal controls, 400 individuals with MCI, and 200 subjects with mild AD
- 50 sites in the United States and Canada
# ADNI Procedures

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Subject%</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.5 Tesla MRI Imaging</td>
<td>100%</td>
</tr>
<tr>
<td>PET Imaging</td>
<td>50%</td>
</tr>
<tr>
<td>3 Tesla MRI Imaging</td>
<td>25%</td>
</tr>
<tr>
<td>ApoE and genetic banking</td>
<td>100%</td>
</tr>
<tr>
<td>Biomarker Collection</td>
<td>100%</td>
</tr>
<tr>
<td>CSF for Biomarkers</td>
<td>20-50%</td>
</tr>
</tbody>
</table>
Inclusion/Exclusion Criteria

General Inclusion Criteria

- Hachinski less than or equal to 4
- Age between 55-90
- Stability of Permitted Medications (4 weeks)
- Geriatric Depression Scale less than 6
- Study partner with 10+ hr/wk contact, accompanies to visits
- Visual and auditory acuity adequate for neuropsychological testing
- Good general health with no diseases precluding enrollment.
- Women must be sterile or two years past childbearing potential
- Willing and able to complete a 3 year imaging study
- 6 grades education or work history
- Must speak English/Spanish fluently
<table>
<thead>
<tr>
<th>Criteria</th>
<th>NL</th>
<th>MCI</th>
<th>AD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Memory Complaints</td>
<td>None.</td>
<td>Memory complaint that is verified by a study partner</td>
<td>Memory complaint that is verified by a study partner.</td>
</tr>
<tr>
<td>Memory Function</td>
<td>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): a) more than or equal to 9 for 16 or more years of education</td>
<td>Abnormal memory function documented by scoring below the education adjusted cutoff on the Logical Memory II subscale (Delayed Paragraph Recall) from the Wechsler Memory Scale Revised (maximum score = 25): a) less than or equal to 8 for 16 or more years</td>
<td>Abnormal memory function documented by scoring below the education adjusted cutoff on the Logical Memory II subscale (Delayed Paragraph Recall) from the Wechsler Memory Scale Revised (the maximum score is 25): a) less than or equal to 8 for 16 or more</td>
</tr>
<tr>
<td>MMSE</td>
<td>24 - 30 Inclusive</td>
<td>24 - 30 Inclusive</td>
<td>20 - 26 Inclusive</td>
</tr>
<tr>
<td>CDR</td>
<td>CDR = 0 Memory Box Score = 0</td>
<td>CDR = 0.5 Memory Box Score = 0</td>
<td>CDR = 0.5 or 1 Memory Box Score = 0.5</td>
</tr>
<tr>
<td>General Cognition</td>
<td>Cognitively normal, No Cognitive or ADL impairment</td>
<td>Cognition and ADL preserved such that a diagnosis of Alzheimer's disease cannot be made by the site physician at the time of the screening visit</td>
<td>NINCDS/ADRDA criteria for probable AD.</td>
</tr>
</tbody>
</table>
Key ADNI Inclusion Criteria

- Commitment to Neuroimaging
- DNA for ApoE testing and banking
- Blood and Urine for Biomarkers
- Commitment to provide CSF samples (20-50% of study population)
- Not enrolled in other clinical trials
ADNI Start-up Requirements

- MRI Certification
  *Phantom Imaging*
  *Volunteer Imaging (after IRB approval)*
- PET Certification
  *Phantom Imaging*
- ADCS Site Personnel Certification
  *CDR, ADAS*

Sites must complete all certifications prior to scheduling screening visits!
Subject Enrollment

- Each site is expected to enroll 16 subjects (4 AD, 4 NL, 8 MCI)
- Enrollment could be limited if sites do not recruit a minimum of 20% to LP.
- Subject allocation to sub-studies (MRI and PET) will depend on site’s capabilities, subject’s consent, and centralized subject allocation.
Screening Process

1. Email sent notifying Study Coordinator of fail and reminding to cancel Screen MRI.

2. Cell assignment incorporates APOE results. If subject consents to both PET and 3T, cell assignment will notify site which scan to schedule for Baseline.
Online Databases: Data Management

- Enter and Manage own data
- Resolve queries in real time
- Reports on Site Performance
- Reports on overall Study Progress

Project Menu > Site Menu > ADNI Subject Menu > Visit Men

Subject: 1-aaa

Required CRF's for each visit:

- Screening Visit
  View PDF
- Baseline Visit
  View PDF
- Registry
- Registry
- Participant Demographic Information
- Vital Signs
- Study Partner Demographic Information
- Neuropsychological Battery
- Medical History
- Neuropsychiatric Inventory Q
ADCS ADNI Team

- Team Leader: Anthony Gamst, PhD
- Team Coordinator: Sarah Walter
- Informatics: Devon Gessert
- Systems: Mike Biglan
- Statistician: Youyan Xu

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