Visit Date: __ __ / __ __ / __ __ __ __ (mm/dd/yyyy)

Visit Name: ____________________

Subject ID: __ __ - __ __ __ __ Subject initials: __ __ __

A. Informed Consent
   1. Date Informed Consent Signed: __ __ / __ __ / __ __ __ __ (mm/dd/yyyy)
   2. Version Number of Consent Form: __________
      ☐ N/A
   3. Version Date of Consent Form: __ __ / __ __ / __ __ __ __ (mm/dd/yyyy)
      ☐ N/A

B. Disease Stage
   1. Current Parkinson’s disease stage:
      ☐ Early untreated
      ☐ Moderate
      ☐ Advanced
      ☐ N/A - Healthy Control

C. Future Research
   1. Did the subject consent to be contacted by site for future research?  ☐ Yes  ☐ No
<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Visit Date:</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Visit Name:</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Subject ID:</strong></td>
<td>__ __ __ - __ __ __ __</td>
</tr>
<tr>
<td><strong>Subject initials:</strong></td>
<td>__ __ _</td>
</tr>
</tbody>
</table>

1. **Date of collection:** __ __ / __ __ / __ __ __ __ (mm/dd/yyyy)

2. **Sex:**
   - ○ Female
   - ○ Male

3. **Date of birth:** __ __ / __ __ / __ __ __ __ (mm/dd/yyyy)

4. **Ethnicity (Select ONLY one):**
   - ○ Hispanic or Latino
   - ○ Not Hispanic or Latino
   - ○ Unknown
   - ○ Not Reported

5. **Race:**
   - ○ Select all races with which the subject identifies:
     - ■ American Indian or Alaska Native
     - ■ Native Hawaiian or other Pacific Islander
     - ■ Asian
     - ■ White
     - ■ Black or African-American
   - ○ Unknown
   - ○ Not reported

6. **Years of education (0-30):** _____________

7. **Primary referral source:**
   - ○ Site Personnel
   - ○ Fox Trial Finder
   - ○ Family or Friend
   - ○ Newspaper/TV/Radio
   - ○ Online blog/news/social media
   - ○ Educational event
   - ○ MJFF Communication
   - ○ Study Website
   - ○ Primary Doctor or Medical Care Provider
   - ○ Support group
   - ○ PPMI study
   - ○ Biofind study
A. **Study Inclusion Criteria**

To be considered eligible for the study, subjects must meet the following criteria:

<table>
<thead>
<tr>
<th>No</th>
<th>Yes</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>1.</td>
<td>☐</td>
</tr>
<tr>
<td>2.</td>
<td>☐</td>
</tr>
<tr>
<td>3.</td>
<td>☐</td>
</tr>
<tr>
<td>4.</td>
<td>☐</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>5.</td>
<td>☐</td>
</tr>
<tr>
<td>6.</td>
<td>☐</td>
</tr>
</tbody>
</table>

B. **Study Exclusion Criteria**

Subjects who meet any of the following criteria are not eligible for participation in the study:

<table>
<thead>
<tr>
<th>No</th>
<th>Yes</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>1.</td>
<td>☐</td>
</tr>
<tr>
<td>2.</td>
<td>☐</td>
</tr>
<tr>
<td>3.</td>
<td>☐</td>
</tr>
<tr>
<td>4.</td>
<td>☐</td>
</tr>
<tr>
<td>5.</td>
<td>☐</td>
</tr>
</tbody>
</table>
No  Yes

6. ○ ○ Have received botulinum toxin injections to the submandibular gland within the past year.

7. ○ ○ Conditions that preclude safe performance of routine lumbar puncture, such as prohibitive lumbar spinal disease.

8. ○ ○ Conditions that preclude the safe performance of the flexible sigmoidoscopy procedure or may interfere with obtaining evaluable colonic tissue biopsies, including a prior colonoscopy with any significant finding (e.g. polyp with a positive finding, ulcerative colitis, Crohn's disease, inflammatory disease).

9. ○ ○ Conditions that preclude the safe performance of the submandibular gland procedure or may interfere with obtaining evaluable submandibular tissue biopsies, including any previous or active significant disease affecting the submandibular gland (e.g. inflammatory disease, infection, tumor).

10. ○ ○ Conditions that preclude the safe performance of the skin punch biopsy procedure or may interfere with obtaining evaluable skin tissue biopsies, including any previous or active significant dermatological disease (e.g. previous biopsy with any of the following findings: inflammatory disease, scar tissue, psoriasis, keloid formation, skin cancer).

11. ○ ○ Any other medical or psychiatric condition or laboratory abnormality, which in the opinion of the investigator would preclude participation.

12. ○ ○ Use of investigational drugs or devices within 30 days prior to the screening visit.

13. ○ ○ Has other significant neurological disorders (clinically significant stroke, brain tumor, hydrocephalus, epilepsy, other neurodegenerative disorders, encephalitis, repeated head trauma, polyneuropathy).

14. ○ ○ Has significant autonomic dysfunction (symptomatic orthostasis, hypotension or urinary incontinence) suggestive of an atypical parkinsonism

15. ○ ○ Has atypical features of parkinsonism including but not limited to supranuclear gaze palsy, early recurrent falls, corticospinal track abnormalities, cerebellar abnormalities, significant cognitive dysfunction.

__________________________________________________________________________
Investigator's Signature

__________________________________________________________________________
Date of Signature (mm/dd/yyyy)

S4 Recorder's Initials _______
Eligibility HC v1.0 07/29/2015
A. Study Inclusion Criteria

To be considered eligible for the study, subjects must meet the following criteria:

<table>
<thead>
<tr>
<th>No</th>
<th>Yes</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td></td>
</tr>
<tr>
<td>2.</td>
<td></td>
</tr>
<tr>
<td>3.</td>
<td></td>
</tr>
</tbody>
</table>

B. Study Exclusion Criteria

Subjects who meet any of the following criteria are not eligible for participation in the study:

<table>
<thead>
<tr>
<th>No</th>
<th>Yes</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td></td>
</tr>
<tr>
<td>2.</td>
<td></td>
</tr>
<tr>
<td>3.</td>
<td></td>
</tr>
<tr>
<td>4.</td>
<td></td>
</tr>
<tr>
<td>5.</td>
<td></td>
</tr>
<tr>
<td>6.</td>
<td></td>
</tr>
<tr>
<td>7.</td>
<td></td>
</tr>
<tr>
<td>8.</td>
<td></td>
</tr>
<tr>
<td>9.</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>10.</td>
<td></td>
</tr>
<tr>
<td>11.</td>
<td></td>
</tr>
<tr>
<td>12.</td>
<td></td>
</tr>
<tr>
<td>13.</td>
<td></td>
</tr>
<tr>
<td>15.</td>
<td></td>
</tr>
<tr>
<td>16.</td>
<td></td>
</tr>
</tbody>
</table>

Investigator’s Signature ___________________________ Date of Signature (mm/dd/yyyy) ___________________________

S4 Recorder’s Initials ________

Eligibility HC v1.0 07/29/2015
Visit Date: __ __ / __ __ / __ __ __ __ (mm/dd/yyyy)

Visit Name: ____________________

Subject ID: __ __ - __ __ __ __ Subject initials: __ __ __

1. Date of collection: __ __ / __ __ / __ __ __ __ (mm/dd/yyyy)

2. Month and year of first symptoms as confirmed by history obtained by the physician? __ __ / __ __ __ __ (mm/yyyy)

3. Month and year of Initial Diagnosis? __ __ / __ __ __ __ (mm/yyyy)

4. Diagnostic Features/Criteria (as evident on clinical assessment of the patient):

<table>
<thead>
<tr>
<th>Feature</th>
<th>Assessment Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>4-6 Hz Rest Tremor</td>
<td>○ Present ○ Absent ○ Unknown</td>
</tr>
<tr>
<td>Bradykinesia</td>
<td>○ Present ○ Absent ○ Unknown</td>
</tr>
<tr>
<td>Rigidity</td>
<td>○ Present ○ Absent ○ Unknown</td>
</tr>
<tr>
<td>Asymmetric Onset</td>
<td>○ Present ○ Absent ○ Unknown</td>
</tr>
<tr>
<td>Substantial Response to Dopaminergic Therapy</td>
<td>○ Present ○ Absent ○ Unknown</td>
</tr>
</tbody>
</table>

5. Side of body most affected: ○ Left ○ Right ○ Symmetric

6. Has the subject started dopaminergic therapy? ○ Yes ○ No

a. Date dopaminergic therapy started: __ __ / __ __ / __ __ __ __ (mm/dd/yyyy)

b. Motor fluctuation? ○ Yes ○ No

i. Wearing off? ○ Yes ○ No

1. Date started: __ __ / __ __ / __ __ __ __ (mm/dd/yyyy)

c. Does the subject experience dyskinesia? ○ Yes ○ No

i. Date first appeared: __ __ / __ __ / __ __ __ __ (mm/dd/yyyy)
### Medical History

#### A. Date medical history taken:

\[ \text{Visit Date: \_\_/ \_\_/ \_\_ \_\_ \_\_} \] (mm/dd/yyyy)

#### B. General Medical History

Does the participant/subject have a history of any medical problems/conditions in the following body systems?

- [ ] No (leave rest of form blank)
- [ ] Yes

*Use BODY SYSTEM numeric code to categorize medical history:

<table>
<thead>
<tr>
<th>Body System*</th>
<th>Medical History Term (one item per line)</th>
<th>Start Date (mm/dd/yyyy)</th>
<th>Still present?</th>
<th>If No, End Date (mm/dd/yyyy)</th>
</tr>
</thead>
<tbody>
<tr>
<td>01 Constitutionalsymptoms</td>
<td>06 Abdominal/GI</td>
<td>11 Endocrine</td>
<td>[ <em><strong>/</strong><strong>/</strong></em>___ ]</td>
<td>[ ] Yes</td>
</tr>
<tr>
<td>02 Eyes</td>
<td>07 Musculoskeletal</td>
<td>12 Blood/Hematology/Lymphatic</td>
<td>[ <em><strong>/</strong><strong>/</strong></em>___ ]</td>
<td>[ ] Yes</td>
</tr>
<tr>
<td>03 Ears, Nose, Mouth, Throat</td>
<td>08 Skin</td>
<td>13 Immunological/Allergy</td>
<td>[ <em><strong>/</strong><strong>/</strong></em>___ ]</td>
<td>[ ] Yes</td>
</tr>
<tr>
<td>04 Cardiovascular</td>
<td>09 Neurological/CNS</td>
<td>14 Gynecological/Urological/Renal</td>
<td>[ <em><strong>/</strong><strong>/</strong></em>___ ]</td>
<td>[ ] Yes</td>
</tr>
<tr>
<td>05 Respiratory</td>
<td>10 Psychiatric</td>
<td>15 Other, specify</td>
<td>[ <em><strong>/</strong><strong>/</strong></em>___ ]</td>
<td>[ ] Yes</td>
</tr>
</tbody>
</table>

---

S4
Medical History v. 1.0 7/20/2015
PI Initials_______
Recorder's Initials_______
<table>
<thead>
<tr>
<th>Body System*</th>
<th>Medical History Term (one item per line)</th>
<th>Start Date (mm/dd/yyyy)</th>
<th>Still present?</th>
<th>If No, End Date (mm/dd/yyyy)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>○ Yes</td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td>○ No</td>
<td></td>
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<td></td>
<td>○ Yes</td>
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<td></td>
<td></td>
<td>○ No</td>
<td></td>
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<td></td>
<td>○ Yes</td>
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<td></td>
<td></td>
<td></td>
<td>○ No</td>
<td></td>
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<td><em><strong>/</strong>__/</em>___</td>
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<td>○ Yes</td>
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<td>○ No</td>
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<td>○ Yes</td>
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<td>○ No</td>
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<td></td>
<td>○ Yes</td>
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<td></td>
<td></td>
<td></td>
<td>○ No</td>
<td></td>
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<td></td>
<td></td>
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<td></td>
<td></td>
<td>○ Yes</td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td>○ No</td>
<td></td>
</tr>
<tr>
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<td></td>
<td><em><strong>/</strong>__/</em>___</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*If more space is needed please reprint this page.
Date of collection: __ __ / __ __/ __ __ __ __ (mm/dd/yyyy)

Indicate if any of the following relatives has a history of PD or Parkinsonism...

2. Biological mother:       ○ Yes       ○ No
3. Biological father:       ○ Yes       ○ No
4. Maternal grandmother:   ○ Yes       ○ No
5. Maternal grandfather:   ○ Yes       ○ No
6. Paternal grandmother:   ○ Yes       ○ No
7. Paternal grandfather:   ○ Yes       ○ No

Indicate if the subject has any of the following family members...

<table>
<thead>
<tr>
<th>Relative</th>
<th>Number of Family Members</th>
<th>Number known with PD or Parkinsonism</th>
</tr>
</thead>
<tbody>
<tr>
<td>8. Biological children</td>
<td></td>
<td></td>
</tr>
<tr>
<td>9. Full siblings</td>
<td></td>
<td></td>
</tr>
<tr>
<td>10. Half siblings</td>
<td></td>
<td></td>
</tr>
<tr>
<td>11. Maternal aunts</td>
<td></td>
<td></td>
</tr>
<tr>
<td>12. Maternal uncles</td>
<td></td>
<td></td>
</tr>
<tr>
<td>13. Paternal aunts</td>
<td></td>
<td></td>
</tr>
<tr>
<td>14. Paternal uncles</td>
<td></td>
<td></td>
</tr>
<tr>
<td>15. Other, specify relationship(s):</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Relative</th>
<th>Number of Family Members</th>
<th>Number known with PD or Parkinsonism</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### Date of collection:

The date of collection is specified in the form. 

#### Cranial nerves

<table>
<thead>
<tr>
<th>Nerves</th>
<th>a) Assessment Result</th>
<th>b) Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>❌ Normal</td>
<td>○ Abnormal</td>
</tr>
<tr>
<td></td>
<td>❌ Not tested</td>
<td>○ Unable to test</td>
</tr>
<tr>
<td>II</td>
<td>❌ Normal</td>
<td>○ Abnormal</td>
</tr>
<tr>
<td></td>
<td>❌ Not tested</td>
<td>○ Unable to test</td>
</tr>
<tr>
<td>III, IV, VI</td>
<td>❌ Normal</td>
<td>○ Abnormal</td>
</tr>
<tr>
<td></td>
<td>❌ Not tested</td>
<td>○ Unable to test</td>
</tr>
<tr>
<td>V</td>
<td>❌ Normal</td>
<td>○ Abnormal</td>
</tr>
<tr>
<td></td>
<td>❌ Not tested</td>
<td>○ Unable to test</td>
</tr>
<tr>
<td>VII</td>
<td>❌ Normal</td>
<td>○ Abnormal</td>
</tr>
<tr>
<td></td>
<td>❌ Not tested</td>
<td>○ Unable to test</td>
</tr>
<tr>
<td>VIII</td>
<td>❌ Normal</td>
<td>○ Abnormal</td>
</tr>
<tr>
<td></td>
<td>❌ Not tested</td>
<td>○ Unable to test</td>
</tr>
<tr>
<td>IX, X</td>
<td>❌ Normal</td>
<td>○ Abnormal</td>
</tr>
<tr>
<td></td>
<td>❌ Not tested</td>
<td>○ Unable to test</td>
</tr>
<tr>
<td>XI</td>
<td>❌ Normal</td>
<td>○ Abnormal</td>
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<tr>
<td></td>
<td>❌ Not tested</td>
<td>○ Unable to test</td>
</tr>
<tr>
<td>XII</td>
<td>❌ Normal</td>
<td>○ Abnormal</td>
</tr>
<tr>
<td></td>
<td>❌ Not tested</td>
<td>○ Unable to test</td>
</tr>
</tbody>
</table>
### 3. Muscle Strength

<table>
<thead>
<tr>
<th>Test Area</th>
<th>a) Assessment Result</th>
<th>b) Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Right Arm</td>
<td>○ Normal  ○ Abnormal</td>
<td>○ Not tested ○ Unable to test</td>
</tr>
<tr>
<td>Left Arm</td>
<td>○ Normal  ○ Abnormal</td>
<td>○ Not tested ○ Unable to test</td>
</tr>
<tr>
<td>Right Leg</td>
<td>○ Normal  ○ Abnormal</td>
<td>○ Not tested ○ Unable to test</td>
</tr>
<tr>
<td>Left Leg</td>
<td>○ Normal  ○ Abnormal</td>
<td>○ Not tested ○ Unable to test</td>
</tr>
</tbody>
</table>

### 4. Coordination

<table>
<thead>
<tr>
<th>Test Area</th>
<th>a) Assessment Result</th>
<th>b) Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Right Arm</td>
<td>○ Normal  ○ Abnormal</td>
<td>○ Not tested ○ Unable to test</td>
</tr>
<tr>
<td>Left Arm</td>
<td>○ Normal  ○ Abnormal</td>
<td>○ Not tested ○ Unable to test</td>
</tr>
<tr>
<td>Right Leg</td>
<td>○ Normal  ○ Abnormal</td>
<td>○ Not tested ○ Unable to test</td>
</tr>
<tr>
<td>Left Leg</td>
<td>○ Normal  ○ Abnormal</td>
<td>○ Not tested ○ Unable to test</td>
</tr>
</tbody>
</table>
5. Sensation

<table>
<thead>
<tr>
<th>Test Area</th>
<th>a) Assessment Result</th>
<th>b) Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Right Arm</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>○ Normal</td>
<td>○ Abnormal</td>
</tr>
<tr>
<td></td>
<td>○ Not tested</td>
<td>○ Unable to test</td>
</tr>
<tr>
<td>Left Arm</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>○ Normal</td>
<td>○ Abnormal</td>
</tr>
<tr>
<td></td>
<td>○ Not tested</td>
<td>○ Unable to test</td>
</tr>
<tr>
<td>Right Leg</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>○ Normal</td>
<td>○ Abnormal</td>
</tr>
<tr>
<td></td>
<td>○ Not tested</td>
<td>○ Unable to test</td>
</tr>
<tr>
<td>Left Leg</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>○ Normal</td>
<td>○ Abnormal</td>
</tr>
<tr>
<td></td>
<td>○ Not tested</td>
<td>○ Unable to test</td>
</tr>
</tbody>
</table>

6. Muscle Stretch Reflexes

<table>
<thead>
<tr>
<th>Test Area</th>
<th>a) Assessment Result</th>
<th>b) Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Right Arm</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>○ Absent</td>
<td>○ Hypoactive</td>
</tr>
<tr>
<td></td>
<td>○ Normal</td>
<td>○ Hyperactive, no clonus</td>
</tr>
<tr>
<td></td>
<td>○ Hyperactive clonus</td>
<td>○ Not tested</td>
</tr>
<tr>
<td></td>
<td>○ Unable to test</td>
<td></td>
</tr>
<tr>
<td>Left Arm</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>○ Absent</td>
<td>○ Hypoactive</td>
</tr>
<tr>
<td></td>
<td>○ Normal</td>
<td>○ Hyperactive, no clonus</td>
</tr>
<tr>
<td></td>
<td>○ Hyperactive clonus</td>
<td>○ Not tested</td>
</tr>
<tr>
<td></td>
<td>○ Unable to test</td>
<td></td>
</tr>
<tr>
<td>Right Leg</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>○ Absent</td>
<td>○ Hypoactive</td>
</tr>
<tr>
<td></td>
<td>○ Normal</td>
<td>○ Hyperactive, no clonus</td>
</tr>
<tr>
<td></td>
<td>○ Hyperactive clonus</td>
<td>○ Not tested</td>
</tr>
<tr>
<td></td>
<td>○ Unable to test</td>
<td></td>
</tr>
<tr>
<td>Left Leg</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>○ Absent</td>
<td>○ Hypoactive</td>
</tr>
<tr>
<td></td>
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</tr>
<tr>
<td></td>
<td>○ Hyperactive clonus</td>
<td>○ Not tested</td>
</tr>
<tr>
<td></td>
<td>○ Unable to test</td>
<td></td>
</tr>
</tbody>
</table>
7. **Plantar Response**

<table>
<thead>
<tr>
<th>Test Area</th>
<th>a) Assessment Result</th>
<th>b) Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Right</td>
<td>○ Flexor</td>
<td>○ Extensor</td>
</tr>
<tr>
<td></td>
<td>○ Indeterminate</td>
<td>○ Not tested</td>
</tr>
<tr>
<td></td>
<td>○ Unable to test</td>
<td></td>
</tr>
<tr>
<td>Left</td>
<td>○ Flexor</td>
<td>○ Extensor</td>
</tr>
<tr>
<td></td>
<td>○ Indeterminate</td>
<td>○ Not tested</td>
</tr>
<tr>
<td></td>
<td>○ Unable to test</td>
<td></td>
</tr>
</tbody>
</table>
Visit Date: __ __ / __ __ / __ __ __ __ (mm/dd/yyyy)
Visit Name: ____________________
Subject ID: __ __ - __ __ __ __Subject initials: __ __ __

A. Date of Visit: __ __ / __ __ / __ __ __ __ (mm/dd/yyyy)

B. | Body System                                      | a) Abnormality Present? | b) Describe Abnormality | c) Is Abnormality Clinically Significant? |
   |                                               | ○ Yes ○ No ○ Not Done   |                          |                                          |
1. Skin                                        | ○ Yes ○ No ○ Not Done   | ○ Yes ○ No              |                                          |
2. Head/Neck/Lymphatic                         | ○ Yes ○ No ○ Not Done   | ○ Yes ○ No              |                                          |
3. Eyes                                        | ○ Yes ○ No ○ Not Done   | ○ Yes ○ No              |                                          |
4. Ears, Nose, Throat                          | ○ Yes ○ No ○ Not Done   | ○ Yes ○ No              |                                          |
5. Lungs                                       | ○ Yes ○ No ○ Not Done   | ○ Yes ○ No              |                                          |
6. Cardiovascular (including peripheral vascular) | ○ Yes ○ No ○ Not Done   | ○ Yes ○ No              |                                          |
7. Abdomen                                     | ○ Yes ○ No ○ Not Done   | ○ Yes ○ No              |                                          |
8. Musculoskeletal                             | ○ Yes ○ No ○ Not Done   | ○ Yes ○ No              |                                          |
9. Neurological                                | ○ Yes ○ No ○ Not Done   | ○ Yes ○ No              |                                          |
10. Psychiatric                                | ○ Yes ○ No ○ Not Done   | ○ Yes ○ No              |                                          |
11. Other:                                     | ○ Yes ○ No              | ○ Yes ○ No              |                                          |

C. Comments: __________________________________________________________________________________
__________________________________________________________________________________________
__________________________________________________________________________________________
__________________________________________________________________________________________
__________________________________________________________________________________________

S4 Recorder’s Initials ________
Physical Exam v. 1.0 7/20/2015
1. Date of visit: __ __ / __ / __ __ __ (mm/dd/yyyy)
2. Heart rate/pulse: ______ / beats per minute
3. Respiratory rate: ______ / breaths per minute
4. Blood pressure: ______ / ______ mmHg (systolic/diastolic)
5. Temperature measurement: ______ °C
   a. Temperature method: ○ Oral ○ Axillary ○ Tympanic ○ Other, specify: _____________
6. Weight: ______ . ____ kilograms [Conversion: kilograms = pounds x 0.4536]
7. Height (standing): ______ . ____ centimeters [Conversion: centimeters = inches x 2.54]
Visit Date: __ __ / __ __ / __ __ __ __ (mm/dd/yyyy)

Visit Name: ________________

Subject ID: __ __ - __ __ __ __ Subject initials: __ __ __

A. Date of assessment: __ __ / __ __ / __ __ __ __ (mm/dd/yyyy)

B. Is the subject taking medication for their Parkinson's?  ○ Yes  ○ No (Skip Part III (On medication))
   1. If so, was the subject able to abstain from taking their medication before coming in for the visit?
      ○ Yes  ○ No (Skip Part III (Off medication))
   2. What is the date and time the subject last took their Parkinson's medication?
      Date: __ __ / __ __ / __ __ __ __ (mm/dd/yyyy)  Time: __ __:__ __ (24-hour clock)
Visit Date: __ __ / __ __ / __ __ __ __ (mm/dd/yyyy)

Visit Name: ____________________

Subject ID: __ __ - __ __ __ __ Subject initials: __ __ __

### Part I

1.a. Source of information
   - Patient
   - Caregiver
   - Patient + Caregiver

1.1. Cognitive impairment ____

1.2. Hallucinations and psychosis ____

1.3. Depressed mood ____

1.4. Anxious mood ____

1.5. Apathy ____

1.6. Features of DDS ____

1.6a. Who is filling out questionnaire
   - Patient
   - Caregiver
   - Patient + Caregiver

1.7. Sleep problems ____

1.8. Daytime sleepiness ____

1.9. Pain and other sensations ____

1.10. Urinary problems ____

1.11. Constipation problems ____

1.12. Light headedness on standing ____

1.13. Fatigue ____

### Part II

2.1. Speech ____

2.2. Saliva and drooling ____

2.3. Chewing and swallowing ____

2.4. Eating tasks ____

2.5. Dressing ____

2.6. Hygiene ____

2.7. Handwriting ____

2.8. Doing hobbies and other activities ____

2.9. Turning in bed ____

2.10. Tremor ____

2.11. Getting out of bed ____

2.12. Walking and balance ____

2.13. Freezing ____
Part III (Off medication)

3.3a. Rigidity – Neck ____
3.3b. Rigidity – RUE ____
3.3c. Rigidity – LUE ____
3.3d. Rigidity – RLE ____
3.3e. Rigidity – LLE ____
3.4a. Finger Tapping Right Hand ____
3.4b. Finger Tapping Left Hand ____
3.5a. Hand movements - Right Hand ____
3.5b. Hand movements - Left Hand ____
3.6a. Pronation - Supination Movements Right Hand ____
3.6b. Pronation - Supination Movements Left Hand ____
3.7a. Toe tapping - Right foot ____
3.7b. Toe tapping - Left foot ____
3.8a. Leg agility - Right leg ____
3.8b. Leg agility - Left leg ____
3.9. Arising from chair ____
3.10. Gait ____
3.11. Freezing of gait ____
3.12. Postural stability ____
3.13. Posture ____
3.15a. Postural tremor - Right hand ____
3.15b. Postural tremor - Left hand ____
3.16a. Kinetic tremor - Right hand ____
3.16b. Kinetic tremor - Left hand ____
3.17a. Rest tremor amplitude – RUE ____
3.17b. Rest tremor amplitude – LUE ____
3.17c. Rest tremor amplitude – RLE ____
3.17d. Rest tremor amplitude – LLE ____
3.17e. Rest tremor amplitude - Lip/jaw ____
3.18. Constancy of rest ____
   a. Were dyskinesias present during the exam?
      ○ No   ○ Yes
      i. If yes, did these movements interfere with your rating?
         ○ No   ○ Yes
   b. Hoehn and Yahr stage ____
Part IV

4.1. Time spent with dyskinesias ____
4.2. Functional impact of dyskinesias ____
4.3. Time spent in the OFF state ____
4.4. Functional impact of fluctuations ____
4.5. Complexity of motor fluctuations ____
4.6. Painful OFF-state dystonia ____
Visit Date: ___ / ___ / ___ (mm/dd/yyyy)

Visit Name: ____________________

Subject ID: ___ - ___ Subject initials: ___ ___

Part III (On medication)

3a Time medication was taken: ___:___ (24-hour clock)

3b Time of assessment: ___:___ (24-hour clock)

3.1. Speech

3.2. Facial expression

3.3a. Rigidity – Neck

3.3b. Rigidity – RUE

3.3c. Rigidity – LUE

3.3d. Rigidity – RLE

3.3e. Rigidity – LLE

3.4a. Finger Tapping Right Hand

3.4b. Finger Tapping Left Hand

3.5a. Hand movements - Right Hand

3.5b. Hand movements - Left Hand

3.6a. Pronation - Supination Movements Right Hand

3.6b. Pronation - Supination Movements Left Hand

3.7a. Toe tapping - Right foot

3.7b. Toe tapping - Left foot

3.8a. Leg agility - Right leg

3.8b. Leg agility - Left leg

3.9. Arising from chair

3.10. Gait

3.11. Freezing of gait

3.12. Postural stability

3.13. Posture


3.15a. Postural tremor - Right hand

3.15b. Postural tremor - Left hand

3.16a. Kinetic tremor - Right hand

3.16b. Kinetic tremor - Left hand

3.17a. Rest tremor amplitude – RUE

3.17b. Rest tremor amplitude – LUE

3.17c. Rest tremor amplitude – RLE

3.17d. Rest tremor amplitude – LLE

3.17e. Rest tremor amplitude - Lip/jaw

3.18. Constancy of rest

a. Were dyskinesias present during the exam
   ○ No  ○ Yes

i. If yes did these movements interfere with your rating?
   ○ No  ○ Yes

b. Hoehn and Yahr stage. ___
Visit Date: __ __ / __ __ / __ __ __ __ (mm/dd/yyyy)
Visit Name: ____________________
Subject ID: __ __ __ - __ __ __ __ Subject initials: __ __ 

1. Select the description below that best describes the participant’s condition.

- 100% Completely independent. Able to do all chores without slowness, difficulty or impairment. Essentially normal. Unaware of any difficulty
- 90% Completely independent. Able to do all chores with some degree of slowness, difficulty and impairment. Might take twice as long. Beginning to be aware of difficulty.
- 80% Completely independent in most chores. Takes twice as long. Conscious of difficulty and slowness.
- 70% Not completely independent. More difficulty with some chores. Three to four times as long in some. Must spend a large part of the day with chores.
- 60% Some dependency. Can do most chores, but exceedingly slowly and with much effort. Errors; some impossible.
- 50% More dependent. Help with half, slower, etc. Difficulty with everything.
- 40% Very dependent. Can assist with all chores but few alone.
- 30% With effort, now and then does a few chores alone or begins alone. Much help needed.
- 20% Nothing alone. Can be a slight help with some chores. Severe invalid.
- 10% Totally dependent, helpless. Complete invalid.
- 0% Vegetative functions such as swallowing, bladder, and bowel functions are not functioning. Bedridden.
By means of this questionnaire, we would like to find out to what extent in the past month you have had problems with various bodily functions, such as difficulty passing urine, or excessive sweating. Answer the questions by placing a cross in the box which best reflects your situation. If you wish to change an answer, fill in the ‘wrong’ box and place a cross in the correct one. If you have used medication in the past month in relation to one or more of the problems mentioned, then the question refers to how you were while taking this medication. You can note the use of medication on the last page.

1. In the past month, have you had difficulty swallowing or have you choked?
   - Never
   - Sometimes
   - Regularly
   - Often

2. In the past month, has saliva dribbled out of your mouth?
   - Never
   - Sometimes
   - Regularly
   - Often

3. In the past month, has food ever become stuck in your throat?
   - Never
   - Sometimes
   - Regularly
   - Often

4. In the past month, did you ever have the feeling during a meal that you were full very quickly?
   - Never
   - Sometimes
   - Regularly
   - Often

5. Constipation is a blockage of the bowel, a condition in which someone has a bowel movement twice a week or less. In the past month, have you had problems with constipation?
   - Never
   - Sometimes
   - Regularly
   - Often

6. In the past month, did you have to strain hard to pass stools?
   - Never
   - Sometimes
   - Regularly
   - Often

7. In the past month, have you had involuntary loss of stools?
   - Never
   - Sometimes
   - Regularly
   - Often
Visit Date: __ __ / __ __ / __ __ __ __ (mm/dd/yyyy)

Visit Name: ____________________

Subject ID: __ __ __ - __ __ __ __ Subject initials: __ __ 

Questions 8 to 13 deal with problems with passing urine. If you use a catheter you can indicate this by placing a cross in the box "use catheter".

8. In the past month, have you had difficulty retaining urine?
   - Never
   - Sometimes
   - Regularly
   - Often

9. In the past month, have you had involuntary loss of urine?
   - Never
   - Sometimes
   - Regularly
   - Often

10. In the past month, have you had the feeling that after passing urine your bladder was not completely empty?
    - Never
    - Sometimes
    - Regularly
    - Often

11. In the past month, has the stream of urine been weak?
    - Never
    - Sometimes
    - Regularly
    - Often

12. In the past month, have you had to pass urine again within 2 hours of the previous time?
    - Never
    - Sometimes
    - Regularly
    - Often

13. In the past month, have you had to pass urine at night?
    - Never
    - Sometimes
    - Regularly
    - Often

14. In the past month, when standing up have you had the feeling of either becoming lightheaded, or no longer being able to see properly, or no longer being able to think clearly?
    - Never
    - Sometimes
    - Regularly
    - Often

15. In the past month, did you become light-headed after standing for some time?
    - Never
    - Sometimes
    - Regularly
    - Often

16. Have you fainted in the past 6 months?
    - Never
    - Sometimes
    - Regularly
    - Often

17. In the past month, have you ever perspired excessively during the day?
    - Never
    - Sometimes
    - Regularly
    - Often

18. In the past month, have you ever perspired excessively during the night?
    - Never
    - Sometimes
    - Regularly
    - Often
19. In the past month, have your eyes ever been over-sensitive to bright light?

- Never
- Sometimes
- Regularly
- Often

20. In the past month, how often have you had trouble tolerating cold?

- Never
- Sometimes
- Regularly
- Often

21. In the past month, how often have you had trouble tolerating heat?

- Never
- Sometimes
- Regularly
- Often

The following questions are about sexuality. Although we are aware that sexuality is a highly intimate subject, we would still like you to answer these questions. For the questions on sexual activity, consider every form of sexual contact with a partner or masturbation (self-gratification). An extra response option has been added to these questions. Here you can indicate that the situation described has not been applicable to you in the past month, for example because you have not been sexually active. Questions 22 and 23 are intended specifically for men, 24 and 25 for women.

The following 3 questions are only for men

22. In the past month, have you been impotent (unable to have or maintain an erection)?

- Never
- Sometimes
- Regularly
- Often
- Not applicable

23. In the past month, how often have you been unable to ejaculate?

- Never
- Sometimes
- Regularly
- Often
- Not applicable

23.a. In the past month, have you taken medication for an erection disorder? (If so, which medication?)

- No
- Yes: ______________________

Proceed with question 26

The following 2 questions are only for women

24. In the past month, was your vagina too dry during sexual activity?

- Never
- Sometimes
- Regularly
- Often
- Not applicable

25. In the past month, have you had difficulty reaching an orgasm?

- Never
- Sometimes
- Regularly
- Often
- Not applicable
The following questions are for everyone

The questions below are about the use of medication for which you may have or have not needed a doctor’s prescription. If you use medication, also give the name of the substance.

26. In the past month, have you used medication for:
   a. constipation?  
      ☐ ☐
      No Yes: ______________________
   d. urinary problems?  
      ☐ ☐
      No Yes: ______________________
   e. blood pressure?  
      ☐ ☐
      No Yes: ______________________
   f. other symptoms (not symptoms related to Parkinson’s Disease)  
      ☐ ☐
      No Yes: ______________________

© This questionnaire is made available free of charge, with the permission of the authors, to all those undertaking non-profit and profit making research. Future users may be requested to share data for psychometric purposes. Use of this questionnaire in studies should be communicated to the developers. No changes may be made to the questionnaire without written permission. Please use the following reference in publications:


For further information, please contact Dr. J. Marinus, Leiden University Medical Center, Department of Neurology (K5Q), P.O. Box 9600, NL-2300 RC Leiden (email: scopa@lumc.nl).
Form 12
University of Pennsylvania
Smell ID Test

Visit Date: ___/___/____ (mm/dd/yyyy)
Visit Name: ____________________
Subject ID: ___ - ___ ___ Subject initials: ___ ___

Record score from each booklet.

1. Score from booklet #1: ______
2. Score from booklet #2: ______
3. Score from booklet #3: ______
4. Score from booklet #4: ______
5. Comments: _______________________________________________________
   _______________________________________________________
   _______________________________________________________
A. Date of assessment: __/__/___ (mm/dd/yyyy)

1. Visuospatial/Executive: ____ (0-5)

2. Naming: ____ (0-3)

3. Attention
   a. Reading list of digits: ____ (0-2)
   b. Reading list of letters: ____ (0-1)
   c. Serial 7 subtraction: ____ (0-3)

4. Language
   a. Repeat: ____ (0-2)
   b. Fluency: ____ (0-1)

5. Abstraction: ____ (0-2)

6. Delayed Recall: ____ (0-5)

7. Orientation: ____ (0-6)
A.

1. Date of visit: __ __ / __ __/ __ __ __ __ (mm/dd/yyyy)

B.

<table>
<thead>
<tr>
<th>Safety Assessment</th>
<th>a) Abnormality Present?</th>
<th>b) Describe Abnormality</th>
<th>c) Is Abnormality Clinically Significant?</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Blood drawn</td>
<td>○ Yes ○ No ○ Not Done</td>
<td></td>
<td>○ Yes ○ No</td>
</tr>
<tr>
<td>2. ECG collected</td>
<td>○ Yes ○ No ○ Not Done</td>
<td></td>
<td>○ Yes ○ No</td>
</tr>
</tbody>
</table>

C. Reason not collected: __________________________________________________________

________________________________________________________________________________

________________________________________________________________________________
## Pregnancy Test Form

<table>
<thead>
<tr>
<th>Question</th>
<th>Details</th>
</tr>
</thead>
</table>
| **1.** Subject is (choose one): | ○ Male (STOP)  
○ Female but **not** of child-bearing potential (STOP)  
○ Female of child-bearing potential (continue to question 2) |
| **2.** Type of specimen collected for pregnancy test (choose one): | ○ Blood  
○ Urine  
○ Not collected |
| **3.** Date of collection: | __ __ / __ __ / __ __ __ __ (mm/dd/yyyy) |
| **4.** Time of collection: | __ __ : __ __ (24 hour clock) |
| **5.** Test result (choose one): | ○ Pregnant  
○ Not pregnant |
1. Was the scan collected?  ○ Yes  ○ No  
   a. Date of scan: __ __ / __ __/ __ __ __ __ (mm/dd/yyyy)  
   b. For what study was the scan originally collected?  ○ S4  ○ PPMI  
      i. If S4, was SPECT imaging data transferred to the core imaging lab?  ○ Yes  ○ No  

PD Subjects Only  

2. SPECT visual interpretation report indicates the scan is:  
   ○ Consistent with evidence of dopamine transporter deficit  
   ○ Not consistent with evidence of dopamine transporter deficit
<table>
<thead>
<tr>
<th>Form 17</th>
<th>Blood Sampling</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Visit Date:</strong> __ __ / __ __ / __ __ __ __ (mm/dd/yyyy)</td>
<td></td>
</tr>
<tr>
<td><strong>Visit Name:</strong> ____________________</td>
<td></td>
</tr>
<tr>
<td><strong>Subject ID:</strong> __ __ - __ __ __ __</td>
<td></td>
</tr>
<tr>
<td><strong>Subject initials:</strong> __ __</td>
<td></td>
</tr>
</tbody>
</table>

1. Date of visit: __ __ / __ __ / __ __ __ __ (mm/dd/yyyy)
2. Date of last intake of food: __ __ / __ __ / __ __ __ __ (mm/dd/yyyy)
3. Time of last intake of food: __ __:__ __ (24-hour clock)
4. Fasting status:  ○ Fasted (minimum of 8 hours)  ○ Low Fat Diet  ○ Not Fasted, No Low Fat Diet
5. Is subject on medication for PD?  ○ Yes  ○ No
   a. Date of most recent PD medication dosing: __ __ / __ __ / __ __ __ __ (mm/dd/yyyy)
   b. Time of most recent PD medication dosing: __ __:__ __ (24-hour clock)

**Paxgene RNA**

6. Was blood for Paxgene RNA collected?  ○ Yes  ○ No
   a. Time collection completed: __ __:__ __ (24-hour clock)
   b. Date samples were frozen: __ __ / __ __ / __ __ __ __ (mm/dd/yyyy)
   c. Time samples were frozen: __ __:__ __ (24-hour clock)
   d. Number of inversions: __________
   e. Number of tubes: __________
   f. Volume collected:  ○ Complete tube  ○ Incomplete tube
   g. Freezer storage temperature: – __ __ (Celsius)
Visit Date: ___ / ___ / ___ ___ (mm/dd/yyyy)

Visit Name: ____________________

Subject ID: ___ __ - ___ ___ ___ Subject initials: ___ ___

Plasma

7. Was blood for Plasma collected? ○ Yes ○ No
   a. Time collection completed: ___ : ___ (24-hour clock)
   b. Time of centrifugation: ___ : ___ (24-hour clock)
   c. Rate of centrifugation: ___ ___ (xg)
   d. Duration of centrifugation: ___ (minutes)
   e. Temperature at which tube was centrifuged: ○ Room temperature ○ Refrigerated
   f. Total volume aliquoted after centrifuging: ___ (mL)
   g. Total number of aliquot tubes: ___
   h. Time samples were frozen: ___ : ___ (24-hour clock)
   i. Freezer storage temperature: – ___ (Celsius)

Whole Blood

8. Was whole blood for future analysis collected? ○ Yes ○ No
   a. Time collection completed: ___ : ___ (24-hour clock)
   b. Volume collected: ○ Complete tube ○ Incomplete tube
   c. Time samples were frozen: ___ : ___ (24-hour clock)
   d. Freezer storage temperature: – ___ (Celsius)

9. Was whole blood for CBC with reticulocytes collected? ○ Yes ○ No
   a. Time collection completed: ___ : ___ (24-hour clock)
Visit Date: __ __ / __ __ / __ __ __ __ (mm/dd/yyyy)

Visit Name: ____________________

Subject ID: __ __ - __ __ __ __ Subject initials: __ __ __

Serum

10. Was blood for serum collected?  ○ Yes  ○ No
   a. Time collection completed: __ __:__ __(24-hour clock)
   b. Time of centrifugation: __ __:__ __ (24-hour clock)
   c. Rate of centrifugation: __ __ __ __(xg)
   d. Duration of centrifugation: __ __ (minutes)
   e. Temperature at which tube was centrifuged:  ○ Room temperature  ○ Refrigerated
   f. Total volume aliquoted after centrifuging: __ __(mL)
   g. Total number of aliquot tubes: __ __
   h. Time samples were frozen: __ __:__ __ (24-hour clock)
   i. Freezer storage temperature: – __ __(Celsius)

DNA

11. Was blood for DNA collected?  ○ Yes  ○ No
   a. Time collection completed: __ __:__ __(24-hour clock)
   b. Number of tubes: __ __

Volume collected: ○ Complete tube ○ Incomplete tube

Complete Procedural follow-up at day 7 (+/-2days)
### Form 18 Saliva Sampling

**Visit Date:** __ __ / __ __ / __ __ __ __ (mm/dd/yyyy)

**Visit Name:** ____________________

**Subject ID:** __ __ - __ __ __ __ **Subject initials:** __ __ __

---

1. **Date of visit:** __ __ / __ __ / __ __ __ __ (mm/dd/yyyy)

2. **Tobacco use?**  ○ Current  ○ Former  ○ Never
   a. **Time since last use?** __ __  ○ Days  ○ Weeks  ○ Months  ○ Years

3. **Alcohol use?**  ○ Current  ○ Former  ○ Never
   a. **Time since last use?** __ __  ○ Days  ○ Weeks  ○ Months  ○ Years

4. **Saliva sample collected:**  ○ Not Done  ○ Collected  ○ Partial Collection  ○ Attempted, no collection
   a. **Hours since last intake of food or liquid?** __ __
   b. **Hours since last use of oral hygiene products?** __ __
   c. **Collection start time:** __ __: __ __ (24 hour clock)
   d. **Collection end time:** __ __: __ __ (24 hour clock)
   e. **Amount of saliva collected:** __ __.__(ml)
   f. **Amount of protease inhibitor added to saliva sample:** __ __ __ (microliters)
   g. **Protease inhibitor manufacturer:** ______________________
   h. **Protease inhibitor lot #:** _____________
   i. **Time centrifuge was begun:** __ __: __ __ (24 hour clock)
   j. **Rate of centrifugation:** __ __ __ __ (xg)
   k. **Duration of centrifugation:** __ __ (minutes)
   l. **Total number of supernatant aliquot tubes collected:** __ __
   m. **Indicate temperature at which tubes were centrifuged:** ○ Room temperature  ○ Refrigerated
   n. **Time tubes placed in freezer:** __ __: __ __ (24 hour clock)
   o. **Storage temperature:** – __ ___(Celsius)
1. Date of visit: __ __ / __ __ / __ __ __ __ (mm/dd/yyyy)

2. Lumbar puncture for collection of CSF:
   - ○ Not Done   ○ Collected   ○ Partial Collection   ○ Attempted, no collection
     a. If collection was not completed, why?
        ______________________________________________________________________________________
        ______________________________________________________________________________________

A. Pre Procedure

1. Date of last intake of food: __ __ / __ __ / __ __ __ __ (mm/dd/yyyy)

2. Time of last intake of food: __ __:__ __ (24-hour clock)

3. Fasting status:   ○ Fasted (minimum of 8 hours)   ○ Low Fat Diet   ○ Not Fasted, No Low Fat Diet

4. Is subject on medication for PD?   ○ Yes   ○ No
   a. Date of most recent PD medication dosing: __ __ / __ __ / __ __ __ __ (mm/dd/yyyy)
   b. Time of most recent PD medication dosing: __ __:__ __ (24-hour clock)

5. Heart rate/pulse: _______/beats per minute

6. Respiratory rate: _______/breaths per minute

7. Blood Pressure: _______ / _______ mmHg (systolic/diastolic)

8. Temperature measurement: _______ °C
B. Procedure

1. Time CSF collection completed: __:__ (24-hour clock)

2. Indicate needle used to collect CSF:
   - 20g Quincke (sharp beveled) needle
   - 22g Quincke (sharp beveled) needle
   - 25g Quincke (sharp beveled) needle
   - 22g Sprotte (atraumatic) needle
   - 24g Sprotte (atraumatic) needle (preferred)
   - Other Specify: ______________

3. Indicate method of collecting the CSF:
   - Gravity
   - Syringe suction

4. Lumbar puncture performed at the:
   - L2-L3 Interspace
   - L3-L4 Interspace
   - L4-L5 Interspace
   - Other Specify: __________

5. Subject position when lumbar puncture performed:
   - Sitting, leaned over (preferred)
   - Lying, curled up on side
   - Other Specify: __________

6. Was part of the sample sent to local lab for analyses?  ○ Yes  ○ No
   a. If no why not?____________________________________
   b. White blood cell count: __ __ __
      i. Unit:  ○ Per Cubic Millimeter  ○ Per Microliter  ○ Per Liter
   c. Red blood cell count: __ __ __
      i. Unit:  ○ Per Cubic Millimeter  ○ Per Microliter  ○ Per Liter
   d. Total protein: __ __ __
      i. Unit:  ○ mg/dL  ○ g/dL  ○ g/L
Visit Date: __ __ / __ __ / __ __ __ __ (mm/dd/yyyy)

Visit Name: ____________________

Subject ID: __ __ - __ __ __ __ Subject initials: __ __ __

7. Was a fluoroscopy performed? ○ Yes ○ No
   a. Date of fluoroscopy: __ __ / __ __ / __ __ __ __ (mm/dd/yyyy)

8. Was a lumbar spine film performed? ○ Yes ○ No
   a. Date of lumbar spine film: __ __ / __ __ / __ __ __ __ (mm/dd/yyyy)

9. Time CSF was centrifuged: __ __:__ __ (24-hour clock) (Within 15 minutes from sample collection)

10. Rate of centrifugation for the CSF sample: __ __ __ __(xg)

11. Duration of centrifugation: ___ (minutes)

12. Temperature at which CSF tube was centrifuged: ○ Room temperature ○ Refrigerated

13. Time CSF sample aliquoted: __ __:__ __ (24-hour clock)

14. Total volume of CSF aliquoted after centrifuging: __ __ (milliliters)

15. Total number of aliquot tubes: __ __

16. Was part of sample discarded due to a bloody tap? ○ Yes ○ No

17. Time samples were frozen: __ __:__ __ (24-hour clock)

18. Storage temperature if placed in freezer: – __ __(Celsius)

C. Post Procedure Vitals

1. Heart rate/pulse: _______/beats per minute

2. Respiratory rate: _______/breaths per minute

3. Blood Pressure: _______/_______ mmHg (systolic/diastolic)

4. Temperature measurement: _______ °C

Complete Procedural follow-up at day 7 (+/-2days)
<p>| | | |</p>
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<td><strong>Visit Date:</strong></td>
<td>_ _ / _ _ / _ _ _ _ (mm/dd/yyyy)</td>
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<tr>
<td><strong>Visit Name:</strong></td>
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<tr>
<td><strong>Subject ID:</strong></td>
<td>_ _ - _ _ _ _ Subject initials: _ _ _</td>
<td></td>
</tr>
</tbody>
</table>

1. **Date of visit:** _ _ / _ _ / _ _ _ _ (mm/dd/yyyy)
2. **Skin biopsy collected:**
   - ☐ Not Done
   - ☐ Collected
   - ☐ Partial Collection
   - ☐ Attempted, no collection
   
   a. If collection was not completed why?

   _____________________________________________________________
   _____________________________________________________________

3. **Type of anesthesia used?**
   - ☐ Lidocaine
   - ☐ None
   - ☐ Other Specify: ______________
   - Formalin Manufacturer: _______________________

4. **Formalin Lot#:** ______________

5. **Zamboni Manufacturer:** ________________________

6. **Zamboni Lot#:** ______________

7. **Use of 3 mm punch biopsy tool?**
   - ☐ Yes
   - ☐ No
   
   a. If another device was used please list: ______________

8. **Comments:**
   _____________________________________________________________
   _____________________________________________________________
   _____________________________________________________________
   _____________________________________________________________

**S4 Recorder’s Initials ______**

Skin Biopsy v. 1.0 9/4/2015
9. Cervical Paravertebral Biopsy:

<table>
<thead>
<tr>
<th>Peach Cassette #</th>
<th># of samples in cassette</th>
<th>Side of biopsy</th>
<th>Closure</th>
<th>Time of biopsy (24-hour clock)</th>
<th>Type of fixative used</th>
<th>Time placed in fixative (24-hour clock)</th>
<th>Time sample was chilled (24-hour clock)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Right</td>
<td>Steri-strip/bandaid</td>
<td>— : — —</td>
<td>Formalin</td>
<td>— : — —</td>
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<tr>
<td></td>
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<td>Left</td>
<td>Suture</td>
<td>— : — —</td>
<td>Zamboni's</td>
<td>— : — —</td>
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<td></td>
<td>Right</td>
<td>Steri-strip/bandaid</td>
<td>— : — —</td>
<td>Formalin</td>
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<td>Left</td>
<td>Suture</td>
<td>— : — —</td>
<td>Zamboni's</td>
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</tbody>
</table>
### Form 20

**Skin Biopsy**

Visit Date: __/__/__ (mm/dd/yyyy)

Visit Name: ____________________

Subject ID: __-__-__Subject initials: __ __

---

**10. Distal Thigh Biopsy:**

<table>
<thead>
<tr>
<th>White Cassette #</th>
<th># of samples in cassette</th>
<th>Side of biopsy</th>
<th>Closure</th>
<th>Time of biopsy (24-hour clock)</th>
<th>Type of fixative used</th>
<th>Time placed in fixative (24-hour clock)</th>
<th>Time sample was chilled (24-hour clock)</th>
</tr>
</thead>
<tbody>
<tr>
<td>________</td>
<td>_________________________</td>
<td>__Right</td>
<td>__Steri-strip/bandaid/Suture</td>
<td><em><strong><strong>:</strong></strong></em></td>
<td>__Formalin/Zamboni's</td>
<td><em><strong><strong>:</strong></strong></em></td>
<td><em><strong><strong>:</strong></strong></em></td>
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<tr>
<td>________</td>
<td>_________________________</td>
<td>__Left</td>
<td>__Steri-strip/bandaid/Suture</td>
<td><em><strong><strong>:</strong></strong></em></td>
<td>__Formalin/Zamboni's</td>
<td><em><strong><strong>:</strong></strong></em></td>
<td><em><strong><strong>:</strong></strong></em></td>
</tr>
</tbody>
</table>

Complete Procedural follow-up at day 7 (+/-2days)
1. Date of visit: __ __ / __ __ / __ __ __ __ (mm/dd/yyyy)

2. Colon biopsy collected:  □ Not Done   □ Collected   □ Partial Collection   □ Attempted, no collection
   a. If collection was not completed, why?
      ______________________________________________________________________________________
      ______________________________________________________________________________________

A. Pre Procedure Vitals

1. Heart rate/pulse: _______/beats per minute
2. Respiratory rate: _______/breaths per minute
3. Blood Pressure: _______ / _______ mmHg (systolic/diastolic)
4. Temperature measurement: _______ °C

B. Procedure

1. Sedation used for procedure?   □ Yes   □ No
   a. If yes please list sedative administered: __________________________
2. Formalin Manufacturer: _________________
3. Formalin Lot#: ________________
4. Were radial jaw forceps used?   □ Yes   □ No
   a. If another device was used please list: __________________________
5. Time for completion of biopsy procedure: __ __:__ __(24-hour clock)
6. Number of tissue samples collected: _________________

S4 Recorder's Initials ________
Colon Biopsy v.1.0 9/4/2015
Visit Date: __ __ / __ __ / __ __ __ __ (mm/dd/yyyy)

Visit Name: ____________________

Subject ID: __ __ __ - __ __ __ __ Subject initials: __ __ __

7. Biopsy Cassette assignment:

<table>
<thead>
<tr>
<th>Biopsy#</th>
<th>Tan Cassette#</th>
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<tbody>
<tr>
<td>1</td>
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<td>4</td>
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<td>7</td>
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<td>8</td>
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</tr>
</tbody>
</table>

8. Time sample placed in formalin: __ __:__ __ (24-hour clock)

9. Time sample chilled: __ __:__ __ (24-hour clock)

10. Comments: __________________________________________________________________________

____________________________________________________________________________________

C. Post Procedure Vitals

1. Heart rate/pulse: _______/beats per minute

2. Respiratory rate: _______/breaths per minute

3. Blood Pressure: _______/_______ mmHg (systolic/diastolic)

4. Temperature measurement: _______ ºC

Complete Procedural follow-up at day 7 (+/-2days)
1. Date of visit: __ / __ / __ __ __ __ (mm/dd/yyyy)

2. Submandibular gland biopsy collected:
   - Not Done  Collected  Partial Collection  Attempted, no collection
   a. If collection was not completed, why?
      ____________________________________________________________________
      ____________________________________________________________________

A. Pre Procedure Vitals
1. Heart rate/pulse: _______/beats per minute
2. Respiratory rate: _______/breaths per minute
3. Blood Pressure: _______ / _______ mmHg (systolic/diastolic)
4. Temperature measurement: _______ ºC

B. Procedure
1. Type of anesthesia used?  ○ Lidocaine  ○ None  ○ Other Specify: ____________
2. Formalin Manufacturer: ____________________________
3. Formalin Lot#: ______________
4. Use of 16-gauge core biopsy needle?  ○ Yes  ○ No
   a. If another device was used please list: ______________________
5. Side of biopsy procedure:  ○ Right  ○ Left
6. Time of completion of biopsy procedure: __ __:__ __ (24-hour clock)
7. Number of tissue samples collected: ____________

Biopsy Cassette assignment – divide all samples between two cassettes:

Recorder’s Initials _________

Submandibular Gland Biopsy v. 1.0 8/31/2015
Visit Date: __ / __ / ______ (mm/dd/yyyy)
Visit Name: __________________
Subject ID: __ __ __ - __ __ __ __ Subject initials: __ __

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<tr>
<th>Biopsy#</th>
<th>Pink Cassette#</th>
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<tbody>
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<td>4</td>
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<td>5</td>
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</tbody>
</table>

8. Comments: ______________________________________
               ______________________________________
               ______________________________________

9. Time sample placed in formalin: __ __:__ __(24-hour clock)

10. Time sample chilled: __ __:__ __(24-hour clock)

C. Post Procedure Vitals

1. Heart rate/pulse: _______/beats per minute

2. Respiratory rate: _______/breaths per minute

3. Blood Pressure: _______/ _______ mmHg (systolic/diastolic)

4. Temperature measurement: _______ °C

Complete Procedural follow-up at day 7 (+/-2days)
### Form 23 - Procedural Follow-up

| Visit Date: ____/__/____ (mm/dd/yyyy) |
| Visit Name: ______________________ |
| Subject ID: ___-______ Subject initials: ___ ___ |

1. Procedure this follow-up call is associated with (check all that apply):
   - [ ] DaTscan
   - [ ] Skin Biopsy
   - [ ] Lumbar Puncture
   - [ ] Colon Biopsy
   - [ ] Submandibular Biopsy

2. Was telephone contact attempted between days 5 and 9 post-procedure?  ○ Yes  ○ No (Complete 2.a)
   a. Reason contact was not attempted: ____________________________
      ____________________________
      ____________________________

3. Was telephone contact made following this procedure?  ○ Yes (Complete 3.a)  ○ No
   a. Date of telephone contact: ____/__/____ (mm/dd/yyyy)

4. Was the subject queried about Adverse Events?  ○ Yes  ○ No

5. Was the subject queried about any changes in Concomitant Medications?  ○ Yes  ○ No

**Note**: If subject reports any Adverse Events or changes in Concomitant Medications, please complete the appropriate eCRF.
Concomitant Medications

Visit Name: _______________________

Subject ID: _____ - _____ Subject initials: _____

<table>
<thead>
<tr>
<th>Dose Units</th>
<th>Dose Frequency</th>
<th>Route</th>
</tr>
</thead>
<tbody>
<tr>
<td>g = gram</td>
<td>BID = twice daily</td>
<td>HS = at bedtime</td>
</tr>
<tr>
<td>mcg = microgram</td>
<td>TID = three times a day</td>
<td>QWK = weekly</td>
</tr>
<tr>
<td>mL = milliliter</td>
<td>QID = four times a day</td>
<td>QMT = Monthly</td>
</tr>
<tr>
<td>mg = milligram</td>
<td>q2h = every 2 hours</td>
<td>PRN = as needed</td>
</tr>
<tr>
<td>mcL = microliter</td>
<td>q4h = every 4 hours</td>
<td>OTH = other</td>
</tr>
<tr>
<td></td>
<td>q6h = every 6 hours</td>
<td>UNK = unknown</td>
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<tr>
<td></td>
<td>q8h = every 8 hours</td>
<td>NA = Not applicable</td>
</tr>
<tr>
<td></td>
<td>QAM = one dose in morning</td>
<td>IV</td>
</tr>
<tr>
<td></td>
<td>QPM = one dose in evening</td>
<td>IM</td>
</tr>
<tr>
<td></td>
<td>QD = once daily</td>
<td>PO</td>
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<tr>
<td></td>
<td>QOD = alternating day (every other day)</td>
<td>SC</td>
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<td>PR</td>
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<td>Sublingual</td>
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<td>Topical</td>
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<td>Other</td>
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<tr>
<th>Indication</th>
<th>Treatment Name / Medication Name</th>
<th>Total (or average) Daily Dose</th>
<th>Dose Units</th>
<th>Dose Frequency</th>
<th>If PRN, Average Monthly Frequency</th>
<th>Route</th>
<th>Start Date (mm/dd/yyyy)</th>
<th>End Date (mm/dd/yyyy)</th>
<th>Ongoing</th>
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S4 Recorder's Initials ________
## Concomitant Medications

**Visit Name:** _______________________

**Subject ID:** __ __ - __ __ __ __ **Subject initials:** __ __ __

<table>
<thead>
<tr>
<th>Indication</th>
<th>Treatment Name / Medication Name</th>
<th>Total (or average) Daily Dose</th>
<th>Dose Units</th>
<th>Dose Frequency</th>
<th>If PRN, Average Monthly Frequency</th>
<th>Route</th>
<th>Start Date (mm/dd/yyyy)</th>
<th>End Date (mm/dd/yyyy)</th>
<th>Ongoing</th>
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**Recorder’s Initials ________

Concomitant Medications Version 1.0_08.13.15
<table>
<thead>
<tr>
<th>Treatment Name / Medication Name</th>
<th>Number of pills per day (Combo drugs only)</th>
<th>Total (or average) Daily Dose</th>
<th>Dose Units</th>
<th>Dose Frequency</th>
<th>If PRN, Average Monthly Frequency</th>
<th>Route</th>
<th>Start Date (mm/dd/yyyy)</th>
<th>End Date (mm/dd/yyyy)</th>
<th>Ongoing</th>
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**Legend:**
- **g** = gram
- **mcg** = microgram
- **mcl** = microliter
- **mg** = milligram
- **mL** = milliliter
- **oz** = ounce
- **oth** = other, specify
- **UNK** = unknown
- **NA** = Not applicable
- **BID** = twice daily
- **TID** = three times a day
- **QID** = four times a day
- **q2h** = every 2 hours
- **Q4h** = every 4 hours
- **q6h** = every 6 hours
- **Q8h** = every 8 hours
- **QAM** = one dose in morning
- **QPM** = one dose in evening
- **QD** = once daily
- **QOD** = alternating day (every other day)
- **HS** = at bedtime
- **QWK** = weekly
- **QMT** = Monthly
- **PRN** = as needed
- **OTH** = other
- **UNK** = unknown
- **NA** = Not applicable
- **IV**
- **IM**
- **PO**
- **SC**
- **PR**
- **Sublingual**
- **Inhaled**
- **Topical**
- **Other**

**Additional Information:**
- Visit Name: _______________________
- Subject ID: __ - __ - __ __ __ __ Subject initials: __ __ __
- Recorder’s Initials ________

Form 24B
Concomitant Medications for PD Version 1.0_08.25.15
## Concomitant Medications for PD

### Visit Name: _______________________

Subject ID: __ __ - __ __ __ __  Subject initials: __ __ __

<table>
<thead>
<tr>
<th>Treatment Name / Medication Name</th>
<th>Number of pills per day (Combo drugs only)</th>
<th>Total (or average) Daily Dose</th>
<th>Dose Units</th>
<th>Dose Frequency</th>
<th>If PRN, Average Monthly Frequency</th>
<th>Route</th>
<th>Start Date (mm/dd/yyyy)</th>
<th>End Date (mm/dd/yyyy)</th>
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S4 Recorder's Initials ________

Concomitant Medications for PD Version 1.0_08.25.15

Recorder's Initials ________
Visit Date: __ __ / __ __ / __ __ __ __ (mm/dd/yyyy)

Visit Name: ____________________

Subject ID: ___ - ___ ___ ___ Subject initials: __ __

1. Date of Adverse Event (AE): __ __ / __ __ / __ __ __ __ (mm/dd/yyyy)

2. Date site became aware of AE: __ __ / __ __ / __ __ __ __ (mm/dd/yyyy)

3. Adverse event term (Use Short Name from CTCAE 4): ___________________________________________

4. Describe the event or problem (include any details relating to diagnosis):

_________________________________________________________________________________________
_________________________________________________________________________________________
_________________________________________________________________________________________
_________________________________________________________________________________________
_________________________________________________________________________________________

5. Is this an exacerbation of a pre-existing condition (existing prior to enrollment)?
   ○ Yes
   ○ No

6. Describe relevant tests/laboratory data, including dates and results.

_________________________________________________________________________________________
_________________________________________________________________________________________
_________________________________________________________________________________________
_________________________________________________________________________________________
_________________________________________________________________________________________

7. Describe other relevant history, including preexisting medical conditions (e.g. allergies, pregnancy, smoking, alcohol use, hepatic / renal dysfunction, etc), if applicable.

_________________________________________________________________________________________
_________________________________________________________________________________________
_________________________________________________________________________________________
_________________________________________________________________________________________
8. Attributes of Adverse Event (check all that apply):
   NOTE: All choices below represent a SAE except “none of the above”
   - ☐ Death: __ __ / __ __ / __ __ __ __ (mm/dd/yyyy)
   - ☐ Life-Threatening
   - ☐ Hospitalization-Initial or Prolonged
   - ☐ Disability
   - ☐ Congenital Anomaly
   - ☐ Required Intervention to Prevent Permanent Impairment/Damage
   - ☐ Important Medical Events as Determined by the Site PI or Designee
   - ☐ None of the Above (non-serious AE)

9. Intensity: NOTE: Please follow CTCAE 4 Guidelines
   - ☐ Mild / Grade I
   - ☐ Moderate / Grade II
   - ☐ Severe / Grade III
   - ☐ Life Threatening / Grade IV
   - ☐ Death / Grade V

Visit Date: __ __ / __ __ / __ __ __ __ (mm/dd/yyyy)
Visit Name: ____________________
Subject ID: __ __ - __ __ __ __ Subject initials: __ __ __

S4 Recorder’s Initials ________
Visit Date: __ / __ / __ __ __ __ (mm/dd/yyyy)

Visit Name: ____________________

Subject ID: __ __ - __ __ __ __ Subject initials: __ __ __

10. Related to study procedure:  ○ Yes  ○ No
   a. Which study procedure is this (S)AE related to?
      ○ Skin Biopsy
      ○ Colon Biopsy
      ○ Submandibular Gland Biopsy
      ○ Lumbar Puncture
      ○ Blood Collected
      ○ DATScan
      ○ Other, specify: __________________________

11. Indicate outcome of the event:
   ○ Continuing
   ○ Resolved
   ○ Resolved with sequelae
      a. If resolved, date of resolution: __ __ / __ __ / __ __ __ __ (mm/dd/yyyy)

12. Did this event result in study termination?
   ○ Yes
   ○ No

___________________________________________ _________________________
Investigator’s Signature  Date of Signature (mm/dd/yyyy)

S4 Recorder’s Initials ______
Adverse Event v. 1.0 7/17/2015
### Form 26: Protocol Deviation

**Visit Date:** __ __ / __ __ / __ __ __ __ (mm/dd/yyyy)

**Visit Name:** ____________________

**Subject ID:** __ __ - __ __ __ __ **Subject initials:** __ __ __

---

1. **Date of protocol deviation:** __ __ / __ __ / __ __ __ __ (mm/dd/yyyy)

2. **Date site became aware of deviation:** __ __ / __ __ / __ __ __ __ (mm/dd/yyyy)

3. **Type of deviation (choose one):**
   - ○ Informed consent (Continue to item 4)
   - ○ Protocol compliance (Skip to item 5)
   - ○ Other (Skip to item 6):

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<tr>
<th><strong>Other:</strong></th>
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4. **Choose the option that best describes the informed consent deviation (choose one):**
   - ○ Failure to obtain informed consent
   - ○ No documentation of informed consent
   - ○ Incomplete documentation of informed consent
   - ○ Informed consent obtained after initiation of study procedures
   - ○ Informed consent obtained by someone other than individuals authorized by IRB to obtain consent
   - ○ Missing signed and dated consent form
   - ○ Subject signed expired or incorrect version of the consent form
   - ○ Other:

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<tr>
<th><strong>Other:</strong></th>
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If you answered item 4, skip to item 6.

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S4  PI Initials________  Recorder’s Initials ________
Protocol Deviation v. 1.0 7/20/2015
5. Choose the option that best describes the protocol compliance deviation (choose one):
   - Enrollment of a subject who did not meet all inclusion/exclusion criteria
   - Failure to conduct a study visit
   - Failure to complete all study procedures at a study visit as specified
   - Study procedures/visits conducted out of window
   - Protocol-specified study therapy not administered as directed
   - Other:

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<th>Other:</th>
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6. Provide a detailed description of the protocol deviation:

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<th>Description</th>
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7. Describe the actions taken to address this deviation:

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<th>Action</th>
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8. Describe the corrective plan to ensure that this deviation does not occur again:


9. Did this deviation result in termination from the study?
   ○ Yes
   ○ No
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<tbody>
<tr>
<td><strong>Form 27</strong></td>
<td><strong>Study Termination</strong></td>
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<tr>
<td>Visit Date: _ _ / _ _ / _ _ _ _ (mm/dd/yyyy)</td>
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<tr>
<td>Visit Name: ____________________</td>
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<tr>
<td>Subject ID: _ _ - _ _ _ _ Subject initials: _ _ _</td>
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1. Date of study termination: _ _ / _ _ / _ _ _ _ (mm/dd/yyyy)

2. Primary reason for termination: (select one)
   - ○ Subject completed study procedures per protocol
   - ○ Subject chose to discontinue the study
   - ○ Site PI chose to discontinue subject participation
   - ○ Subject is lost to follow up
     a. Date of last communication from subject, or clinical update: _ _ / _ _ / _ _ _ _ (mm/dd/yyyy)
   - ○ Death
   - ○ Other, specify: __________________________________________

3. Comments:

   ____________________________________________________________