Pre-Operative Information

1. Age at Time of Surgery: _______ years

2. Disease Duration at Time of Surgery: _______ years _______ months

3. Indication (s) for Surgery:
   - [ ] Tremors
   - [ ] Dyskinesias
   - [ ] Motor Fluctuations
   - [ ] Drug/Medication Side Effects
     - [ ] Insomnolence
     - [ ] Behavioral Effects
     - [ ] Nausea/Vomiting
   - [ ] Other, specify ___________________

4. MRI Findings:  [ ] Normal  [ ] Abnormal
   If Abnormal, comment: ________________________________________________________

5. L-Dopa challenge responses
   - Stim-on time: ________________
   - Stim-off time: ________________
### Intra-Operative Information

1. **Target:**
   - [ ] STN
   - [ ] GPi
   - [ ] Thalamus
   - [ ] PPN
   - [ ] Other, specify _______________________

2. **Procedure:**
   - [ ] Unilateral
     - [ ] Left
     - [ ] Right
   - [ ] Bilateral
     - [ ] Simultaneous
     - [ ] Staged
   - [ ] Other, specify _______________________

3. **AC-PC target coordinates:** _________________________ (specify left and right if procedure is unilateral)

4. **Target Planning Method:**
   - [ ] Direct
   - [ ] Indirect
   - [ ] Atlas
   - [ ] Planning Platform
   - [ ] Imaging
   - [ ] Ventriculography
   - [ ] Other, specify _______________________

5. **Type of Anesthesia:**
   - [ ] General
   - [ ] Light Sedation
   - [ ] Local

6. **Was patient on anti-Parkinsonian Medication(s) during Procedure:**
   - [ ] Yes
   - [ ] No
   - [ ] Unknown

7. **Head Position:**
   - [ ] Elevated
   - [ ] Flat

8. **Frame Type:**
   - [ ] CRW
   - [ ] Leksell
   - [ ] Mini-Frame*
   - [ ] Other, specify _______________________

   *If mini-frame is checked, specify the following:
   - [ ] Medtronic
   - [ ] FHC

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**PD Version 1.1**
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<table>
<thead>
<tr>
<th></th>
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</thead>
<tbody>
<tr>
<td><strong>8. Type of Opening:</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>□ Burr Hole   □ Twist Drill Hole   □ Other, specify _____________</td>
</tr>
<tr>
<td><strong>9. Intra-operative Target Verification:</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>□ Image Guidance Platform</td>
</tr>
<tr>
<td></td>
<td>□ Software</td>
</tr>
<tr>
<td></td>
<td>□ Fluoroscopy</td>
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<tr>
<td></td>
<td>□ Microstimulation</td>
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<tr>
<td></td>
<td>□ Macrostimulation</td>
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<tr>
<td></td>
<td>□ X-ray</td>
</tr>
<tr>
<td></td>
<td>□ Microelectrode recording*</td>
</tr>
<tr>
<td></td>
<td>*If microelectrode recording selected, record the following:</td>
</tr>
<tr>
<td></td>
<td>Number of passes: __________</td>
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<tr>
<td></td>
<td>□ Single electrode recording</td>
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<td></td>
<td>□ Multiple-electrode recording (BEN-GUN)</td>
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<tr>
<td></td>
<td>Number of electrodes: __________</td>
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<tr>
<td><strong>10. Method to Secure Lead:</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>□ Mini-plate</td>
</tr>
<tr>
<td></td>
<td>□ Manufacturer’s Specific Locking Device</td>
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<tr>
<td></td>
<td>□ Other, specify ___________________________</td>
</tr>
<tr>
<td><strong>11. Use of Externalization:</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>□ Yes   □ No   □ Unknown</td>
</tr>
</tbody>
</table>
12. Lead and IPG Models Used:
   - □ Lead 3387
   - □ Lead 3389
   - □ IPG Soletra
   - □ IPG Kinetra
   - □ IPG Activa PC
   - □ IPG Activa RC
   - □ Medtronic
   - □ Other, specify ___________________________

13. Total Time in the Operating Room:
    _______ hours _______ minutes

Post-Operative Information

1. Post-operative Target Verification:
   - □ CT
   - □ MRI
   - □ Other, please specify: ___________________________

2. Following optimization, ___ weeks after surgery (fill in blank), were anti-Parkinsonism medications reduced?
   - □ Yes, % reduction: ________________  □ No  □ N/A  □ Unknown

3. Following optimization, were anti-Parkinsonism medications added?
   - □ Yes  □ No  □ N/A  □ Unknown
4. After optimization, what were the stimulation parameters?
   Monopolar: ___________________
   Bipolar: ________________

<table>
<thead>
<tr>
<th>Left Brain</th>
<th>Right Brain</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amplitude Range: _______ Volts</td>
<td>Amplitude Range: _______ Volts</td>
</tr>
<tr>
<td>Frequency Range: _______ Hz</td>
<td>Frequency Range: _______ Hz</td>
</tr>
<tr>
<td>Pulse Width Range: _______ µsec</td>
<td>Pulse Width Range: _______ µsec</td>
</tr>
<tr>
<td>Mean: _______________________</td>
<td>Mean: _______________________</td>
</tr>
<tr>
<td>Range: _______________________</td>
<td>Range: _______________________</td>
</tr>
</tbody>
</table>

5. L-Dopa challenge responses
   Stim-on time: ________________
   Stim-off time: ________________

6. Hardware Replacements: □ N/A (Skip to #7)
   □ Lead, # replaced: _______
   □ IPG, # replaced: __________
   □ Extender, # replaced: __________

7. Was lead repositioned in patient: □ N/A (Skip to #8)
   □ Yes  □ No  □ Unknown
   If yes, please select reason lead repositioned:
   □ Poor positioning
   □ Mechanical breakdown
   □ Infection
   □ Other, specify _______________________________
8. Surgical Complications:  □ N/A

Complication:  □ Intra-operative:  □ Post-operative:

- □ Hemorrhage
- □ Infarct
- □ Seizure
- □ Cardiovascular
- □ Change of mental status
- □ Other, specify ________________
- □ Hemorrhage
- □ Infarct
- □ Infection
- □ Seizure
- □ Mechanical Malfunction
- □ Electrode
- □ Device
- □ Other, specify ________________

Aborted Procedure(s):  □ Yes  □ No  □ Unknown

If Yes:  
A. Number of aborted procedures: ____________
B. Reason aborted:  □ Seizure

- □ Infarct
- □ Cardiovascular (e.g., arrhythmia, heart attack, etc)
- □ Change in mental status
- □ Other, specify _____________________________

Location of complication, if intracranial: __________________________

Complication related to:  □ Surgery
- □ Device
  - □ Electrode
  - □ IPG
  - □ Other, specify ________________

Was complication expected?  □ Expected  □ Unexpected

Severity:  □ Mild  □ Moderate  □ Severe  □ Life-threatening/Disabling  □ Fatal/Death

Action Taken:  □ None  □ Non-study Treatment Required

Outcome:  □ Recovered/Resolved  □ Recovered/Resolved with Sequelae  □ Recovering/Resolving
- □ Not Recovered/Not Resolved  □ Fatal  □ Unknown
GENERAL INSTRUCTIONS

This case report form (CRF) contains data elements related to the treatment of Parkinson’s disease where central nervous system function is abnormal, but structure/anatomy is normal.

Important note: None of the data elements included on this CRF Module is classified as Core (i.e., strongly recommended for all Parkinson’s disease clinical studies to collect). All of the data elements are classified as supplemental (i.e., non Core) and should only be collected if the research team considers them appropriate for their study. Please see the Data Dictionary for element classifications.

SPECIFIC INSTRUCTIONS

Please see the Data Dictionary for definitions for each of the data elements included in this CRF Module.

The CRF includes most of the instructions available for the data elements at this time. Two elements have some additional instructions not included on the CRF:

- **Age at time of surgery** – This element is not considered Core. Please refer to the Date of Birth element on the General Demographics form to derive age. If age is necessary to capture on this form, it may be added.

- **Surgical Complications** – In order to prevent duplication of data collection, the General Adverse Event form will be considered Core for clinical trials. If the information on that form does not completely capture what is needed, the surgical complications section can be supplemental.