Case Report # Neurosurgery Date:

## 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

1. MRI Findings: [ ]  Normal [ ]  Abnormal

If Abnormal, comment:

1. L-Dopa challenge responses

Stim-on time:

Stim-off time:

## Intra-Operative Information

1. The table below consists of two columns. Column 1 describes the target of the surgery and column 2 describes the procedure used for the surgery. Please identify the target by marking the corresponding checkbox in column 1. Please also identify the procedure by marking the coresponding checkbox in column 2.

| Target | Procedure |
| --- | --- |
| **[ ]**  STN**[ ]**  GPi**[ ]**  Thalamus**[ ]**  PPN**[ ]**  Other, specify | **[ ]**  Unilateral**[ ]**  Left**[ ]**  Right**[ ]**  Bilateral**[ ]**  Simultaneous**[ ]**  Staged**[ ]**  Other, specify |

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

1. Target Planning Method:

**[ ]**  Direct

**[ ]**  Indirect

**[ ]**  Atlas

**[ ]**  Planning Platform

**[ ]**  Imaging

**[ ]**  Ventriculography

**[ ]**  Other, specify:

1. Type of Anesthesia:

**[ ]**  General **[ ]**  Light Sedation **[ ]**  Local

1. Was patient on anti-Parkinsonian Medication(s) during Procedure:

**[ ]**  Yes **[ ]**  No **[ ]**  Unknown

1. Head Position:

**[ ]**  Elevated **[ ]**  Flat

1. Frame Type:

**[ ]**  CRW **[ ]**  Leksell **[ ]**  Mini-Frame\* **[ ]**  Other, specify:

\*If mini-frame is checked, specify the following:

**[ ]**  Medtronic **[ ]**  FHC

1. Type of Opening:

**[ ]**  Burr Hole **[ ]**  Twist Drill Hole **[ ]**  Other, specify:

1. Intra-operative Target Verification:

**[ ]**  Image Guidance Platform

**[ ]**  Software

**[ ]**  Fluoroscopy

**[ ]**  Microstimulation

**[ ]**  Macrostimulation

**[ ]**  X-ray

**[ ]**  Microelectrode recording\*

\*If microelectrode recording selected, record the following:

Number of passes:

**[ ]**  Single electrode recording

**[ ]**  Multiple-electrode recording (BEN-GUN)

Number of electrodes:

1. Method to Secure Lead:

**[ ]**  Mini-plate

**[ ]**  Manufacturer’s Specific Locking Device

**[ ]**  Other, specify

1. Use of Externalization:

**[ ]**  Yes **[ ]**  No **[ ]**  Unknown

1. Lead and IPG Models Used:

**[ ]**  Lead 3387

**[ ]**  Lead 3389

**[ ]**  IPG Soletra

**[ ]**  IPG Kinetra

**[ ]**  IPG Activa PC

**[ ]**  IPG Activa RC

**[ ]**  Medtronic

**[ ]**  Other, specify

1. Total Time in the Operating Room: hours minutes

## Post-Operative Information

1. Post-operative Target Verification:

**[ ]**  CT **[ ]**  MRI **[ ]**  Other, please specify:

1. Following optimization, weeks after surgery (fill in blank), were anti-Parkinsonism medications reduced?

**[ ]**  Yes, % reduction: **[ ]**  No **[ ]**  N/A **[ ]**  Unknown

1. Following optimization, were anti-Parkinsonism medications added?

**[ ]**  Yes **[ ]**  No **[ ]**  N/A **[ ]**  Unknown

1. After optimization, what were the stimulation parameters?

Monopolar: Bipolar:

Left Brain and Right Brain Data Table

| Left Brain | Right Brain |
| --- | --- |
| Amplitude Range: Volts | Amplitude Range: Volts |
| Frequency Range: Hz | Frequency Range: Hz |
| Pulse Width Range: μsec | Pulse Width Range: μsec |
| Mean: | Mean: |
| Range: | Range: |

1. L-Dopa challenge responses:

Stim-on time:

Stim-off time:

1. Hardware Replacements: **[ ]**  N/A (Skip to #7)

**[ ]**  Lead, # replaced:

**[ ]**  IPG, # replaced:

**[ ]**  Extender, # replaced:

1. 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

1. Surgical Complications: **[ ]**  N/A

**Complication:**

[ ] Intra-operative:

**[ ]**  Hemorrhage

**[ ]**  Infarct

**[ ]**  Seizure

**[ ]**  Cardiovascular

**[ ]**  Change of mental status

**[ ]**  Other, specify:

**[ ]**  Device

**[ ]** Post-operative:

**[ ]**  Hemorrhage

**[ ]**  Infarct

**[ ]**  Infection

**[ ]**  Seizure

**[ ]**  Mechanical Malfunction

**[ ]**  Electrode

**[ ]**  Other, specify:

**Aborted Procedure(s):** **[ ]**  Yes **[ ]**  No **[ ]**  Unknown

If Yes:

1. **Number of aborted procedures:**
2. **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.