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.