Case report # Neurosurgery date:

## Pre-Operative Information

1. Age at time of surgery: years
2. Duration of motor signs at time of surgery
   1. Duration of motor signs of Parkinson’s disease: years: months:
   2. Duration of motor fluctuations (specify zero if none): years: months:
   3. Duration of troublesome dyskinesias (specify zero if none): years: months:
3. Indication(s) for DBS (check all that apply):

Medication-resistant tremor

Medication-induced dyskinesia

Motor Fluctuations

Other medication side effects, specify:

Other indication, specify:

1. MRI findings:  Normal  Abnormal

If Abnormal, comment:

1. L-Dopa challenge responses
   1. Version of UPDRS administered:  UPDRS  MDS-UPDRS
   2. UPDRS part 3 score, off levodopa:
      1. Hours off of levodopa:
      2. Hours off of dopamine agonists: (specify which agonists):
   3. UPDRS part 3 score, on medications:

## Intra-Operative Information

1. Structure targeted:

| Target-left brain  (check all that apply) | Target-right brain  (check all that apply) |
| --- | --- |
| STN  Globus pallidus  Ventrolateral thalamus  PPN  Other, specify:  None  Multiple ipsilateral leads  Specify: | STN  Globus pallidus  Ventrolateral thalamus  PPN  Other, specify:  None  Multiple ipsilateral leads  Specify: |

1. Target planning method (check all that apply):

Direct targeting on MRI

Indirect targeting\* on MRI

Indirect targeting\* on CT

Surgical planning software: type:

Surgical planning adjuncts:

Tractography

Automated segmentation of nuclei

Other targeting methods, specify:

\*“Indirect” refers to use of standard coordinates from mid-commissural point or other reference point

1. Type of anesthesia (for lead placement surgery):

General  Moderate sedation  Local only

1. Was patient on anti-parkinsonian medications during procedure:

Yes  No

1. Head position and head fixation:

Head of bed elevated  Head of bed flat

Head fixation to operating room table:  None  Yes, specify:

1. Mechanical guidance for lead insertion:

CRW headframe  Leksell headframe  Single use Mini-Frame (“frameless”)\*

Other, specify:

\*If mini-frame is checked, specify the following (check all that apply):

Medtronic Nexframe  FHC Starfix  MRI interventions Smartframe

Other, specify:

Robotic guidance:  No  Yes If yes, specify platform:

1. Type of opening:

Burr Hole  Twist Drill Hole  Other, specify:

1. Intra-operative target verification (check all that apply):

Fluoroscopy

CT or cone-beam CT

MRI:

Real time during placement

In surgical suite immediately following lead placement

Microelectrode recording and/or microstimulation:

No sedation

Light sedation

Gen anesthesia

Serial single microelectrode recording:

Number of electrode penetrations left: right:

Simultaneous multiple-microelectrode recording left: right:

Number of microelectodes passed simultaneously:

Test stimulation through DBS lead or other microcontact:

No sedation

Light sedation

Gen anesthesia

1. Method to secure lead:

Mini-plate

Manufacturer’s specific locking device

Other, specify:

1. Use of lead externalization:

Yes  No

1. Characteristics of implanted leads and IPG
   1. Brain lead(s):
      1. Number of brain leads inserted: If one, which side?  Right  Left
      2. Directional-8 contact
      3. Directional-other:
      4. Cylindrical-4 contact
      5. Cylindrical-8 contact
      6. Cylindrical-other:
      7. Intercontact spacing (between ends of contacts, not centers):

0.5 mm  1.5 mm  3 mm  Other, specify:

* + 1. Lead manufacturer and model:
  1. Pulse generator(s):
     1. Number of pulse generators inserted: If one, which side?  Right  Left

Primary cell

Rechargeable

* + 1. Pulse generator has sensing function?  Yes  No
    2. Pulse generator manufacturer and model:

1. Total surgical time (incision to closure): hours: minutes:

## Post-Operative Information

1. Post-operative target verification
   1. Modality:  CT  MRI  Other, please specify:
   2. Software utilized for image processing if any (for example LeadDBS, Brainlab Elements, etc.):
   3. AC-PC coordinates for lead tip with respect to midcommissural point (positive values are right, anterior, and superior, negative values are left, posterior, and inferior)

Left: x: y: z: Right: x: y: z:

1. After optimization what were the stimulation parameters?

| Left Brain | Right Brain |
| --- | --- |
| Contact configuration (include percent activation if applicable):  Negative contact(s):  Positive contacts(s):  Directional steering used? No  Yes  Amplitude:  Volts  mA | Contact configuration (include percent activation if applicable):  Negative contact(s):  Positive contacts(s):  Directional steering used? No  Yes  Amplitude:  Volts  mA |
| Frequency: Hz | Frequency: Hz |
| Pulse Width: μsec | Pulse Width: μsec |

If additional right or left leads, specify parameters here:

Stimulation paradigms, specify:

Constant stimulation  Adaptive DBS  Coordinated reset  Other, specify:

1. Following optimization at the stimulation parameters above, were anti-Parkinsonism medications reduced compared to preoperative baseline?  No  Yes, % reduction in levodopa equivalents:
2. Optimal programming limited by stimulation-induced adverse effects: No Yes, specify:
3. Clinical motor outcome:
   1. Version of UPDRS administered:  UPDRS  MDS-UPDRS
   2. UPDRS part 3 score, on DBS, off medication:
   3. UPDRS part 3 score, on DBS, on medication:
4. Number of weeks/months post implantation that these stimulation and parameters and clinical motor outcomes were documented:  Weeks  Months

## Surgical Complications (within 3 months of implantation)

1. Complications not directly involving hardware:  N/A (go to question 2)

Intra-operative:

Hemorrhage If yes:  Symptomatic  Asymptomatic

Seizure

Cardiovascular event

Change of mental status

Other, specify:

Procedure aborted

Post-operative:

Hemorrhage If yes:  Symptomatic  Asymptomatic

Ischemic Infarct

Seizure

Delirium

Other, specify:

Complications severity (version 5.0 of “common terminology criteria for adverse events”):

Mild  Moderate  Severe  Life-threatening/Disabling  Fatal/Death

Action Taken:  None  Treatment required, specify:

Complication outcome (at three months):

Recovered/resolved without neurological deficit

Produced persistent neurological deficit

Other:

1. Hardware-related complications:  N/A

Hardware infection requiring further surgery for removal of hardware components:

Component removed:

Brain lead (specify # of leads removed):

IPG (specify # of IPGs removed):

Lead Extender, (specify # of extenders removed):

Further surgery for replacement or manipulation of a brain lead (for reason other than infection):

If yes, how many:

Select reason lead repositioned:

Poor initial positioning

Migration of lead from initial position

Lead fracture or electrical malfunction

Other, specify:

Further surgery for replacement or manipulation of pulse generator (for reason other than infection):

If yes, how many:

Select reason for pulse generator replacement:

Electrical malfunction

Rechargeable pulse generator flipped over and cannot be recharged

Discomfort

Other, specify:

Further surgery for replacement or manipulation of lead extender (for reason other than infection):

If yes, how many:

Select reason for lead extender replacement:

Electrical malfunction

Discomfort

Other, specify:

## General Instructions

This case report form (CRF) contains data elements related to the treatment of Parkinson’s disease with deep brain stimulator implantation.

Name of CRF was changed from “Functional Neurosurgery” to “Functional Neurosurgery: Deep Brain Stimulation” for Parkinson’s Disease v2.0 since this specifically does not include lesioning procedures. While those are of increasing importance due to advent of focused ultrasound, they would almost never be done in conjunction with DBS so should be a separate form (but it is probably too soon to standardize a form for this given rapid evolution in focused ultrasound).

Important note: None of the data elements included on this CRF Module are 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 Events](https://www.commondataelements.ninds.nih.gov/sites/nindscde/files/Doc/SharedForms/F0009_Adverse_Events.docx) 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.