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 [ ]  YesAmplitude: [ ]  Volts [ ]  mA | Contact configuration (include percent activation if applicable):Negative contact(s):Positive contacts(s):Directional steering used? [ ] No [ ]  YesAmplitude: [ ]  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.