https://cosmiic.org

Example - Early Feasibility Investigational Device Exemption

IDE Section:

Case Report Forms

12. Case Report Forms

This section contains:

12.1. Study Summary Case Report Form

Cervical SCI NNP Study Summary

Version 1.0

PI Initials:

Subject Number:

Test	Dates Completed			
Pre-Surgery				
Screening				
Pre-operative Testing				
Surgery				
NNP Implantation Record				
Rehabilitation Period				
Grasp-Release Test				
Activities of Daily Living Abilities Test				
Trunk-stimulated Reaching Test				
Spinal Cord Independence Measure - III				
Satisfaction Survey				
SF-12				
Annual Follow-up				
NNP Technical and Functional Assessment				
Other				
End of Study				
Adverse Events				
Serious Adverse Events				

Notes

Cervical SCI NNP Study Summary CRF v1.0 - September 18, 2014

12.2. Screening Case Report Form

FES Center Cervical SCI Screening Form

Version 6.0

PI Initials:

Subject Number:

Screening Date(s):

Screening Staff: KLK AMB MWK HAH Other:

Form Completed (Date):

Gender: ☐ Male ☐ Female

Birthdate:

Injury Date:

Right Arm

ASIA Injury Level: C4 C5 C6 C7 Other:

Int. Classification: O Cu

Group: 0 1 2 3 4 Other:

Left Arm

ASIA Injury Level: C4 C5 C6 C7 Other:

Int. Classification: O Cu

Group: 0 1 2 3 4 Other:

Current Medications:

Previous Medical Conditions:

Screening Form, Continued

Inclusion Criteria:
Subjects will be eligible for inclusion in the study if they meet **ALL** of the following Inclusion Criteria:

Criteria	**Yes**	**No**
Skeletally Mature (age > 13 years)	☐	☐
>= 6 months post-injury		
Diagnosis of cervical level spinal cord injury, either complete or incomplete	☐	☐
Peripheral nerve innvervation to upper extremity and trunk muscles, included grade 3/5 or higher stimulated strength (Manual Muscle Test) in at least two of the following muscles in one arm: AdP, AbPB, FPL, EPL/EPB, EDC, FDS, FDP, PQ, ECU, ECRB, ECRL, FCU, FCR, 1DI; and in at least two of the following muscles: left/right gluteus maximus, left/right erector spinae, left/right quadratus lumborum, left/right iliopsoas, and left/right latissimus dorsi	☐	☐
Biceps / brachialis / brachioradialis strength of 2/5 or higher on MMT	☐	☐
Able and willing to take part in study	☐	☐
Medically stable, cleared for surgery	☐	☐

NOTES: _____
_____

Exclusion Criteria:
Subjects will be excluded the study if they meet **ANY** of the following Exclusion Criteria:

Criteria	**Yes**	**No**
Additional neurological conditions	☐	☐
Diabetes with nerve involvement	☐	☐
Adverse interaction between system components and typical EM sources in subject's home and work environments, including wheelchair or other active implantable devices.	☐	☐
Other active implantable device that demonstrates incompatibility with NNP system	☐	☐
Extensive denervation	☐	☐
< 6 months post-injury	☐	☐
Pregnant	☐	☐
Active infection	☐	☐

NOTES: _____
_____

12.3. Pre-Operative Testing Case Report Form

Cervical SCI NNP Pre-operative Testing

Version 1.0

PI Initials: ____

Subject Number: ____

Test	Date Performed	Acceptable Results: Yes	Acceptable Results: No	Follow-up
Urinanalysis and urine culture and sensitivity		☐	☐	
CBC with differential		☐	☐	
ESR (erythrocyte sedimentation rate)		☐	☐	
Basic Metabolic Profile (includes Na+, K+, Cl, BUN, Ca, CO2, Creatinine, anion gap, glucose, estimated GFR)		☐	☐	
PT, PTT, INR		☐	☐	
Hepatic Function Profile (includes Total protein, albumin, Total Bilirubin, Direct Bilirubin, Alkaline)		☐	☐	
Hepatitis B (hepatitis B surface antigen)		☐	☐	
Hepatitis C (HCV)		☐	☐	
Nasal swab for culture and sensitivity		☐	☐	
HIV		☐	☐	
EKG		☐	☐	
CXR		☐	☐	
MRSA Screen (nasal swab)		☐	☐	
Dental Exam		☐	☐	
Renal and Bladder ultrasound		☐	☐	
Skin Assessment		☐	☐	
Pregnancy test ☐N/A		☐	☐	

Comments and Follow-up Testing

Pre-Operative Testing CRF v1.0 - September 12, 2014

12.4. Device Implantation Case Report Form

Cervical SCI NNP System
Implantation Record

Version 2.0

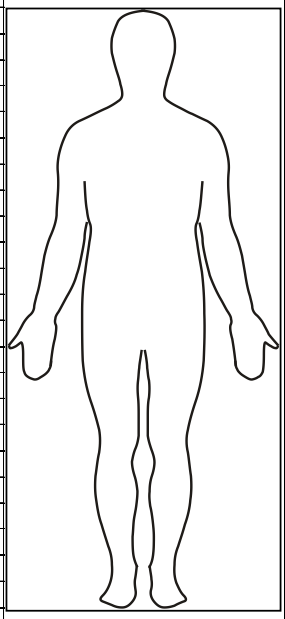
Subject Number: _____ PI Initials: _____

Surgery Date: _____

Surgeon: MWK HAH Other_____

PM1 Serial Number: _____

PM1 Location: L-PEC L-ABD R-PEC R-ABD Other_____

Module Number and Type	Module Serial #	Electrode Serial #	Electrode Style (EP/IN/SP)	Electrode Length (cm)	Muscle	Module Channel ID	Device Location
1 - PG4							
2 - PG4							
3 - PG4							
4 - PG4							
5 - PG4							
6 - PG4							
1 - BP2							
2 - BP2							
3 - BP2							

Network Connections

Number	Serial #	Length	Distal Module	Proximal Module	Comments
1 - NC2					
2 - NC2					
3 - NC2					
4 - NC2					
5 - NC2					
6 - NC2					
7 - NC2					
8 - NC2					
9 - NC2					

12.5. Grasp and Release Test Case Report Form

Grasp Release Test

Form Number: 1 ID:_____

Date:_____Center:_____Coord:_____Invest:_____

Date Recvd:_____Recvd y:_____

Session Information:

Session Number: _____ Evaluator:_____ Location:_____

Entry: ____ Pre-Training:_____ Post-Training:_____ Midterm:____ Exit: _____

Other: ____Describe Other: _____

Pinch Meter: _____ Lateral Calibration:_____ Palmar Calibration:_____

Pinch Force (lbs):

Note: Record uncalibrated scale values

	Lateral			Median	Five Finger			Median	Palmar			
	Median											
+												
-												

Usage/Positioning:

Exercised last night? Y ☐ N ☐ Knee-to-table Seat Angle:

Used today? Y ☐ N ☐ Wheelchair-to-table: Changed? Y ☐ N ☐

Midline to Barrier : Table-to-board:

Wheelchair description:

Wheelchair Ref Point:

Functional Splint (+):

Wrist Position (+)☐ (deg)☐ Direction F ☐ E ☐

Functional Splint (-):

Wrist Postion (-):☐ (deg) Direction ☐ E ☐

Exercise Splint:

Checklist:

System OK? Y ☐ N ☐ ROM completed? Y ☐ N ☐ Video recorded Y ☐ N ☐

System changed? Y ☐ N ☐ Objects cleaned? Y ☐ N ☐ Video reviewed? Y ☐ N ☐

File Dates: Control☐ Exercise: ☐

Lat ☐ Pal: ☐ Other: ☐

Comments:

Grasp Release Test

Form Number: 1

ID:_____
Date:_____Center:_____Coord:_____Invest:_____
Date Recvd:_____Recvd By:_____

Pre-test: Start time: ☐

	NP	Pass?	*Failure Code (list up to three)	*1=prox musc 2=position 3=force 4=control 5=other
	+	Y ☐ N ☐		
Peg	@	Y ☐ N ☐		
	-	Y ☐ N ☐		
	+	Y ☐ N ☐		
Weight	@	Y ☐ N ☐		
	-	Y ☐ N ☐		
	+	Y ☐ N ☐		
Fork	@	Y ☐ N ☐		
		Position 45	**90**	**Tried both? Y ☐ N ☐**
	-	Y ☐ N ☐		
		Position 45	**90**	**Tried both? Y ☐ N ☐**
	+	Y ☐ N ☐		
Block	@	Y ☐ N ☐		
	-	Y ☐ N ☐		
	+	Y ☐ N ☐		
Can	@	Y ☐ N ☐		
	-	Y ☐ N ☐		
	+	Y ☐ N ☐		
Tape	@	Y ☐ N ☐		
	-	Y ☐ N ☐		

Comments:

Continue? Y ☐ N ☐

Grasp Release Test

Form Number: 1 ID:_____

Date:_____Center:_____Coord:_____Invest:_____

Date Recvd:_____Recvd By:_____

Main Test: Start time: ☐

1	NP	Att	Fail	Comp	Comments	Error
Fork	- +/@					
Can	- +/@					
Weight	- +/@					
Tape	+/@ -					
Block	- +/@					
Peg	+/@ -					

Comments:_____

2	NP	Att	Fail	Comp	Comments	Error
Peg	+/@ -					
Weight	+/@ -					
Can	- +/@					
Block	+/@ -					
Fork	- +/@					
Tape	- +/@					

Grasp Release Test

Form Number: 1 ID:_____

Date:_____Center:_____Coord:_____Invest:_____

Date Recvd:_____Recvd By:_____

3	NP	Att	Fail	Comp	Comments	Error
Tape	- +/@					
Fork	+/@ -					
Block	- +/@					
Can	- +/@					
Weight	+/@ -					
Peg	+/@ -					

Comments:_____

Stop time: _____ **Elapsed time:** _____ _____

Pre-test **Main Test**

Have you given this test your best effort? Y ☐ N ☐

Was the test board in an optimal position? Y ☐ N ☐

Was your performance impaired by the evaluator?

	-	+	Comments
Peg	Y ☐ N ☐	Y ☐ N ☐	_____
Weight	Y ☐ N ☐	Y ☐ N ☐	_____
Fork	Y ☐ N ☐	Y ☐ N ☐	_____
Block	Y ☐ N ☐	Y ☐ N ☐	_____
Can	Y ☐ N ☐	Y ☐ N ☐	_____
Tape	Y ☐ N ☐	Y ☐ N ☐	_____

For Pre-training GRT's only: Is this the final pre-training GRT? Y ☐ N ☐ N/A ☐

Comments:_____

_____

_____

_____

12.6. ADL Test Case Report Form

Activity: Method:

ID Code:_____ Date:_____
Center_____Coord_____Investigator_____

Video? Y N Training?___
Retest? Y N Test? ___ Start Time:_____ Finish Time:_____

Tested first with NP? Without NP?

WITH NEUROPROSTHESIS							
PHASE	**PA**	**SU**	**AE**	**OA**	**SA**	**Mode**	**Comments**
Time (sec): 1_____ 2_____ 3_____							

WITHOUT NEUROPROSTHESIS							
PHASE	**PA**	**SU**	**AE**	**OA**	**SA**	**IND**	**Comments**
Time (sec): 1_____ 2_____ 3_____							

Quality + 0 -
Preference + 0 -
Demo All Equip? Y N
Demo All Methods? Y N

Additional Comments:

12.7. Trunk Outcomes Case Report Form

SCI Trunk Reaching Assessment

Version 1.0

PI Initials:

Subject Number:

Forward Bimanual Reaching		Without Stim		Without Stim	
Test No.	Load Lifted	Maximum Elevation (cm)	Maximum Forward (cm)	Maximum Elevation (cm)	Maximum Forward (cm)

Right Arm - Lateral Reaching		Without Stim		Without Stim	
Test No.	Load Lifted	Maximum Elevation (cm)	Maximum Right Side (cm)	Maximum Elevation (cm)	Maximum Right Side (cm)

Left Arm - Lateral Reaching		Without Stim		Without Stim	
Test No.	Load Lifted	Maximum Elevation (cm)	Maximum Left Side (cm)	Maximum Elevation (cm)	Maximum Left Side (cm)

Comments:

Trunk Reaching CRF v10 - September 18, 2014

12.8. Satisfaction Survey Case Report Form

FES Hand Grasp Survey

Questions 1 to 3 ask you to make comparisons of before your FES system was implanted to after your FES system was implanted. Please read the statements and check the appropriate box.

Comparisons Before and After FES Implantation	Strongly Disagree	Disagree	Neither Disagree or Agree	Agree	Strongly Agree
1. If I had the opportunity to do it over again, I would still have the FES system implanted.					
2. I have benefited from the FES system.					
3. The appearance of my hand has improved since my FES system was implanted.					

Questions 4 to 14 ask you to make comparisons of when your FES system is donned and available to use versus when your FES system is not donned or available. Please read the statements and check the appropriate box.

Comparisons With FES and Without FES, after implantation	Strongly Disagree	Disagree	Neither Disagree or Agree	Agree	Strongly Agree
4. I perform more activities with my FES system compared to without my FES system.					
5. I need more adaptive equipment with my FES system compared to without my FES system.					
6. I stay home alone more when my FES system is donned than I do without my FES system.					
7. I spend more time out in the community alone when my FES system is donned than I do without my FES system.					
8. I feel more confident performing activities with my FES system versus without my FES system.					
9. I perform activities faster with my FES system compared to without my FES system.					
10. Activities are harder to perform with my FES system versus without my FES system.					
11. I perform activities more like I used to before I was injured when I use my FES system compared to without my FES system.					
12. I need less help from others (assistance, or attendant time) with my FES system compared to without my FES. (Be sure to consider the amount of assistance you require to perform activities, and the amount of assistance you require to put the system on and off.)					

13. If your reliance on others (attendant time) has changed when your FES system is on how much time per day do you feel it has changed?

___Not applicable - my attendant time has not changed
___My attendant time has increased _____ per day
___My attendant time has decreased _____ per day

13. Please state why you feel that your reliance on others (attendant time) has changed when your FES system is donned compared to without your FES

__Not applicable, my attendant time does not change
__I use more attendant time to put the system on and take it off, and for general maintenance of the system.
__I use more attendant time because I perform more activities with my FES system that require attendant help.
__I use more attendant time because (other, please list):_____
_____
__I use less attendant time because I can perform more tasks independently
__I use less attendant time because I feel more confident on my own.
__I use less attendant time because (other, please list):_____
_____

Questions 15 to 37 are general questions related to the FES system please check the appropriate box.

General Questions: Circle Not applicable for questions 15 and 17 if you do not work or do not go to school, and for 16 and 18 if you do work or go to school.	Strongly Disagree	Disagree	Neither Disagree or Agree	Agree	Strongly Agree
14. My FES system has made a positive impact in my actual work performance. Not Applicable					
15. My FES system has made a positive impact in my potential to return to work. Not Applicable					
16. My FES system has made a positive impact in my actual school performance. Not Applicable					
17. My FES system has made a positive impact in my potential to return to school. Not Applicable					
18. My FES system has made a positive impact in my actual homemaking or home maintenance performance.					
19. My FES system has made a positive impact in my actual volunteer work, recreational, or self-improvement performance.					
20. If I had the money, I would pay for this device.					
21. I think insurance companies should pay for this device.					
22. If the insurance company paid for 80% of this device I would pay for the other 20%, if I had the money.					
23. I would recommend the FES system to other people with spinal cord injury.					
24. My FES system implant has improved the quality of my life.					
25. My FES system is reliable.					
26. I am satisfied with my FES system.					
27. My FES system has made a positive impact on my life.					

XXVIII. Explain how your FES system has impacted your life
Please explain:_____
_____
_____

I. On average how often do you put on your system to use it functionally (that is, not including exercise)?

__7 days per week
__5 to 6 days per week
__3 to 4 days per week
__1 to 2 days per week
__0 days per week

II. On those days when you do not use your system functionally what are the reasons? For the reasons you checked, rank the reasons from most frequent reason (rank = 1) to least frequent reason.

__Not applicable, I use the system everyday,

Reasons:	Rank
__I was ill or in bed,	__
__The system was not working,	__
__I had a skin irritation from the tape or antenna,	__
__I did not have the necessary supplies,	__
__I had problems with my splint,	__
__I did not have an attendant available or the attendant did not have time,	__
__I did not have time,	__
__I was not in the mood,	__
__I was not in the habit of putting it on,	__
__I did not want it on because of the appearance,	__
__I did not need the system,	__
__The system did not provide a benefit to me,	__
__Other_____	__
__Other_____	__

III. On average, how often do you exercise with your FES system?

__7 days per week
__5 to 6 days per week
__3 to 4 days per week
__1 to 2 days per week
__0 days per week

IV. On those days when you do not use your system to exercise what are the reasons? For the reasons you checked, rank the reasons from most frequent reason (rank = 1) to least frequent reason.

__Not applicable, I exercise everyday,

Reasons:	Rank:
__I was ill or in bed,	__
__The system was not working,	__
__I had a skin irritation from the tape or antenna,	__
__I did not have the necessary supplies,	__
__I had problems with my splint,	__
__I did not have an attendant available or the attendant did not have time,	__
__I did not have time,	__
__I was not in the mood,	__
__I was not in the habit of putting it on,	__
__I did not want it on because of appearance,	__
__I had an appointment with the FES team the next day,	__
__It keeps me awake,	__
__I did not feel I needed the exercise, because my hand is strong enough,	__
__Other_____	__
__Other_____	__

V. List the most important tasks for which you use your FES system.

__Not applicable, I either am not using my FES system or I do not find it important for any tasks

My FES system is most important for the following tasks:_____

_____

_____

VI. Approximately how much did you pay for your FES system and/or the surgery? Do not include any amounts for which you got reimbursed.

__I paid _____Dollars

__I paid for part of my FES system and/or surgery but I do not remember how much

__I did not pay for any part of my FES system or the surgeries

__I don't know if I paid for any part of my FES system or the surgery

VII. Please state why you would or would not have the FES system implant performed again:

_____

_____

___

VIII. Please feel free to share any other comments or criticisms with us regarding the FES system implant _____

_____

_____

_____

12.9. SF-12 Case Report Form

SF-12® Patient Questionnaire

Patient Initials _____ _____ _____ Date of Birth: ____/____/____ Patkey: _____

Surgeon Name: _____ Date: _____

Examination Period: _____ Preop (1) _____ 3 Year (4) _____ Immediate Postop (2) _____ 5 Year (5) _____ 1 Year (3) _____ Other (specify) (6): _____

SF-12®:

This information will help your doctors keep track of how you feel and how well you are able to do your usual activities. Answer every question by placing a check mark on the line in front of the appropriate answer. It is not specific for arthritis. If you are unsure about how to answer a question, please give the best answer you can and make a written comment beside your answer.

1. In general, would you say your health is:
   - _____ Excellent (1)
   - _____ Very Good (2)
   - _____ Good (3)
   - _____ Fair (4)
   - _____ Poor (5)

The following two questions are about activities you might do during a typical day. Does YOUR HEALTH NOW LIMIT YOU in these activities? If so, how much?

2. MODERATE ACTIVITIES, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf:
   - _____ Yes, Limited A Lot (1)
   - _____ Yes, Limited A Little (2)
   - _____ No, Not Limited At All (3)

3. Climbing SEVERAL flights of stairs:
   - _____ Yes, Limited A Lot (1)
   - _____ Yes, Limited A Little (2)
   - _____ No, Not Limited At All (3)

During the PAST 4 WEEKS have you had any of the following problems with your work or other regular activities AS A RESULT OF YOUR PHYSICAL HEALTH?

4. ACCOMPLISHED LESS than you would like:
   - _____ Yes (1)
   - _____ No (2)

5. Were limited in the KIND of work or other activities:
   - _____ Yes (1)
   - _____ No (2)

Surgeon Initials _____ Date: _____

Patient Initials _____ _____ _____ Date of Birth: ____/____/____ Patkey: _____

Surgeon Name: _____ Date: _____

Examination Period: _____ Preop (1) _____ 3 Year (4) _____ Immediate Postop (2)
_____ 5 Year (5) _____ 1 Year (3) _____ Other (specify) (6): _____

SF-12® Cont'd:

During the PAST 4 WEEKS, were you limited in the kind of work you do or other regular activities AS A RESULT OF ANY EMOTIONAL PROBLEMS (such as feeling depressed or anxious)?

6. ACCOMPLISHED LESS than you would like:
   _____ Yes (1)
   _____ No (2)

7. Didn't do work or other activities as CAREFULLY as usual:
   _____ Yes (1)
   _____ No (2)

8. During the PAST 4 WEEKS, how much did PAIN interfere with your normal work (including both work outside the home and housework)?
   _____ Not At All (1)
   _____ A Little Bit (2)
   _____ Moderately (3)
   _____ Quite A Bit (4)
   _____ Extremely (5)

The next three questions are about how you feel and how things have been DURING THE PAST 4 WEEKS. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the PAST 4 WEEKS –

9. Have you felt calm and peaceful?
   _____ All of the Time (1)
   _____ Most of the Time (2)
   _____ A Good Bit of the Time (3)
   _____ Some of the Time (4)
   _____ A Little of the Time (5)
   _____ None of the Time (6)

Surgeon Initials _____ Date: _____

Patient Initials _____ _____ _____ Date of Birth: ____/____/____ Patkey: _____

Surgeon Name: _____ Date: _____

Examination Period: _____ Preop (1) _____ 3 Year (4) _____ Immediate Postop (2)
_____ 5 Year (5) _____ 1 Year (3) _____ Other (specify) (6): _____

SF-12® Cont'd:

10. Did you have a lot of energy?
    - _____ All of the Time (1)
    - _____ Most of the Time (2)
    - _____ A Good Bit of the Time (3)
    - _____ Some of the Time (4)
    - _____ A Little of the Time (5)
    - _____ None of the Time (6)

11. Have you felt downhearted and blue?
    - _____ All of the Time (1)
    - _____ Most of the Time (2)
    - _____ A Good Bit of the Time (3)
    - _____ Some of the Time (4)
    - _____ A Little of the Time (5)
    - _____ None of the Time (6)

12. During the PAST 4 WEEKS, how much of the time has your PHYSICAL HEALTH OR EMOTIONAL PROBLEMS interfered with your social activities (like visiting with friends, relatives, etc.)?
    - _____ All of the Time (1)
    - _____ Most of the Time (2)
    - _____ A Good Bit of the Time (3)
    - _____ Some of the Time (4)
    - _____ A Little of the Time (5)
    - _____ None of the Time (6)

Surgeon
Signature_____

Date_____

12.10. Adverse Event Case Report Form

Cervical SCI NNP System

Adverse Event Case Report Form

v2.0 August 28, 2014

Subject ID	
Investigator	
Date form completed:	
Completed by:	
Date of Incident:	
Incident Location:	
Incident Reported By:	
Incident Reported To:	

Type of Incident:

- ☐ Urinary Tract Infection
- ☐ Pressure Sore
- ☐ Infection
- ☐ External Component Failure
- ☐ Implanted Component Failure
- ☐ Other Event

Description of Incident:

Action Taken:

Implanted NNP System usable after incident? Yes ☐ No ☐

Reported to the following:

Physician	Yes ☐	If yes, date:	
	No ☐	If no, reason:	
Clinical Events Committee	Yes ☐	If yes, date:	
	No ☐	If no, reason:	
MHMC IRB	Yes ☐	If yes, date:	
	No ☐	If no, reason:	
VA IRB	Yes ☐	If yes, date:	
	No ☐	If no, reason:	
FDA	Yes ☐	If yes, date:	
	No ☐	If no, reason:	
NIH	Yes ☐	If yes, date:	
	No ☐	If no, reason:	

12.11. Serious Adverse Event Case Report Form

Cervical SCI NNP System

Serious Adverse Event Form

v2.0 August 28, 2014

Outcome of Incident:

- ☐ Death
- ☐ Life-threatening event
- ☐ Inpatient hospitalization
- ☐ Persistent significant disability

*** If the incident does not meet at least one of the above criteria, it is not a serious adverse event. Use the "Adverse Event" form to report it.**

Subject ID	
Investigator	
Date form completed:	
Completed by:	
Date of Incident:	
Incident Location:	
Incident Reported By:	
Incident Reported To:	

Description of Incident:

Action Taken:

Implanted NNP System usable after incident? Yes ☐ No ☐

Reported to the following:

Physician	Yes ☐	If yes, date:	
	No ☐	If no, reason:	
Clinical Events Committee	Yes ☐	If yes, date:	
	No ☐	If no, reason:	
MHMC IRB	Yes ☐	If yes, date:	
	No ☐	If no, reason:	
VA IRB	Yes ☐	If yes, date:	
	No ☐	If no, reason:	
FDA	Yes ☐	If yes, date:	
	No ☐	If no, reason:	
NIH	Yes ☐	If yes, date:	
	No ☐	If no, reason:	

12.12. Annual Follow-Up Form

Cervical SCI NNP Study Annual Follow-up

Version 1.0

PI Initials: ____

Subject Number: ____

Date of Follow-up ____

				Notes
System functional on arrival	☐ Yes	☐ No	☐ Partial:	
Updated Contract Information	☐ Yes	☐ No Change		
Download Datalogging	☐ Yes	☐ No	If no, reason:	
Electrode thresholds	☐ Yes	☐ No	If no, reason:	
Electrode thresholds within expected limits:	☐ Yes	☐ No	If no, complete Adverse Event CRF	
Biopotential signal recording	☐ Yes	☐ No	If no, reason:	
Recording amplitude within expected limits:	☐ Yes	☐ No	If no, complete Adverse Event CRF	
System functional on departure	☐ Yes	☐ No	☐ Partial:	
Adverse events	☐ No new reports			
	☐ New reports. Dated:			

Complaints

Notes

Cervical SCI NNP Study Summary CRF v1.0 - September 18, 2014

12.13. End of Study Form

Cervical SCI NNP System

End of Study Case Report Form

v2.0 August 28, 2014

Subject ID	
Investigator	
Date form completed:	
Completed by:	

Date of Withdrawal from Study		
Implanted Components Removed?	Yes ☐	No ☐
Date of Removal		
External Components Retrieved	Yes ☐	No ☐
Date of Retrieval		

Implanted NNP System functioning prior to withdrawal?

Yes ☐ No ☐ Unk ☐

Reason for Withdrawal