UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934

November 15, 2016
Date of Report (Date of earliest event reported)

HELIUS MEDICAL TECHNOLOGIES, INC.
(Exact name of registrant as specified in its charter)

WYOMING	**36-4787690**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

(Exact name of registrant as specified in charter)

Suite 400, 41 University Drive
Newtown, Pennsylvania, 18940
(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code: (215) 809-2018

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

[ ] Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

[ ] Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

[ ] Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

[ ] Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 1.01 – Entry into a Material Definitive Agreement

On November 21, 2016, Helius Medical Technologies, Inc. (the "Company" or “Helius”) announced that NeuroHabilitation Corporation (“NHC”), a division of Helius, successfully executed an amendment to the sole source cost sharing contract entered into with the U.S. Army Medical Research and Materiel Command (USAMRMC). The contract extends the agreement with USAMRMC to December 31, 2017 and is under the larger Cooperative Research and Development Agreement (“CRADA”) framework with the United States Army. The modification allows Helius to include additional study sites for the clinical trial investigating the safety and effectiveness of the Portable Neuromodulation Stimulator (PoNS™) for the treatment of chronic balance deficits in subjects with mild to moderate traumatic brain injury.

Item 8.01 Other Events.

On November 21, 2016, the Company issued a press release announcing the information discussed in this Item 1.01. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

HELIUS MEDICAL TECHNOLOGIES, INC.

Dated: November 21, 2016

By: /s/ Joyce LaViscount
Joyce LaViscount, Chief Financial Officer

EXHIBIT INDEX

Exhibit No.	Exhibit
10.1	Amendment to Performance Work Statement, dated November 7, 2016
10.2	Performance Work Statement, dated July 1, 2015
10.3	Master Cooperative Research and Development Agreement (CRADA), dated February 1, 2013 and related amendments
99.1	Press Release dated [DATE] (furnished pursuant to Item 1.01).

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

1. CONTRACT ID CODE	PAGE OF PAGES
S	1 | 14

2. AMENDMENT/MODIFICATION NO.	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQ. NO.	5. PROJECT NO.(If applicable)
	07-Nov-2016	SEE SCHEDULE	

6. ISSUED BY	CODE	7. ADMINISTERED BY (If other than item 6)	CODE
USA MED RESEARCH ACQ ACTIVITY 820 CHANDLER ST FORT DETRICK MD 21702-5014	W81XWH	See Item 6	

8. NAME AND ADDRESS OF CONTRACTOR (No., Street, County, State and Zip Code)		
NEUROHABILITATION CORPORATION 41 UNIVERSITY DR STE 400 NEWTOWN PA 18940-1873		9A. AMENDMENT OF SOLICITATION NO.
		9B. DATED (SEE ITEM 11)
	X	10A. MOD. OF CONTRACT/ORDER NO. W81XWH-15-C-0096
	X	10B. DATED (SEE ITEM 13) 01-Jul-2015
CODE 7BGE6	FACILITY CODE	

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

☐ The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offer ☐ is extended, ☐ is not extended.

Offer must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended by one of the following methods: (a) By completing Items 8 and 15, and returning _____ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

12. ACCOUNTING AND APPROPRIATION DATA (If required)

13. THIS ITEM APPLIES ONLY TO MODIFICATIONS OF CONTRACTS/ORDERS. IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.

☐ A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (Specify authority) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.

☐ B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (such as changes in paying office, appropriation date, etc.) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(B).

X C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:
52.243-2 Changes - Cost-Reimbursement

☐ D. OTHER (Specify type of modification and authority)

E. IMPORTANT: Contractor ☐ is not, ☒ is required to sign this document and return 1 copies to the issuing office.

14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.)
Modification Control Number: csult164360

The purpose of this modification is to:
a) Extend the period of performance at no cost to the Government.
b) Incorporate a modified payment schedule.
c) Update the PWS.
d) Update the Additional Information.
e) Update DFARS Clause 252.232-7006 Wide Area Work Flow Payment Instructions.
f) Please see the summary of changes for additional details.
g) All other terms and conditions remain the same.

Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.

15A. NAME AND TITLE OF SIGNER (Type or print)		16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print)	
Joyce LAViscount		TEL 301-619-1346 EMAIL kelly.r.green.civ@mail.mil	
15B. CONTRACTOR/OFFEROR	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA	16C. DATE SIGNED
Joyce LaViscount (Signature of person authorized to sign)	11/11/16	BY (Signature of Contracting Officer)	14 Nov 2016

SECTION SF 30 BLOCK 14 CONTINUATION PAGE

SUMMARY OF CHANGES

SECTION A - SOLICITATION/CONTRACT FORM

The following have been modified:
ADDITIONAL INFORMATION
ADDITIONAL INFORMATION

PROJECT TITLE: Development and U.S. Food and Drug Administration (FDA) Clearance of the Portable Neuromodulation Stimulator (PoNS^{TM}) Device.

The requirement is an R&D contract.

GOVERNMENT POINTS OF CONTACT

The Contract Specialist for this contract is Chris Sult at USAMRAA, ATTN: Chris Sult, MRMC-AAA-SD, 820 Chandler Street, Fort Detrick, MD 21702-5014 or christopher.m.sult.civ@mail.mil or 301-619-1342.

The Contracting Officer for this contract is Kelly Green at USAMRAA, ATTN: Kelly Green, MRMC-AAA-SD, 820 Chandler Street, Fort Detrick, MD 21702-5014 or kelly.r.green.civ@mail.mil or 301-619-1346.

The Contracting Officer's Representative for this contract is Brian Dacanay at USAMMA, ATTN: Brian Dacanay, 693 Neiman Street, Fort Detrick, MD 21702 or Brian.i.dacanay.civ@mail.mil or 301-619-4348.

SECTION C - DESCRIPTIONS AND SPECIFICATIONS

The following have been modified:
PERFORMANCE WORK STATEMENT
Revised PWS – Mod P00001

a) Section 1.1. Changed (TBI) to (mTBI).
b) Section 1.3. Changed eighteen (18) to thirty (30)
c) Section 1.3. Changed the Period of Performance from 01 July 2015 – 31 December 2016 to 01 July 2015 – 31 December 2017.
d) Revised Sections 1.3. and 3.1.4.
e) Added "and when additional sites are added" in the Initial and Subsequent column of the deliverable table for deliverables 6 – 14.

PERFORMANCE WORK STATEMENT (PWS)

Development and U.S. Food and Drug Administration (FDA) Clearance of the Portable Neuromodulation Stimulator (PoNS™) Device

1. Introduction:

The U.S. Amy Medical Materiel Agency (USAMMA) and its parent organization the U.S. Army Medical Research and Materiel Command (USAMRMC) are located at Fort Detrick, in Frederick, Maryland. USAMMA serves as the strategic level, medical logistics generating force, and medical lifecycle management command in support of Army Medicine, the Army Campaign Plan, Military Health System, and Combatant Commands. The agency provides optimal medical acquisition and logistics support and solutions across the full spectrum of military health care missions worldwide. USAMMA has operational oversight of medical materiel acquisition programs and serves as the Army Medical Department's (AMEDD's) command for fielding new medical materiel for the Army's operational forces.

1.1. Background and Purpose:

The U.S. Army is supporting an effort to develop NeuroHabilitation Corporation's (NHC) Portable Neuromodulation Stimulator (PoNS™) as an aid to therapy for chronic balance deficits resulting from a mild to moderate traumatic brain injury (TBI). On 1 February 2013, USAMMA, the U.S. Army Medical Materiel Development Activity (USAMMDA), and NHC established a collaborative relationship, via a Cooperative Research and Development Agreement (CRADA) under 15 USC §3710a, to develop an investigational medical device that employs non-invasive brain stimulation. The PoNS™ device, developed partially under the CRADA, works by applying principles of neuroplasticity that enables the brain to process information in new ways for rehabilitation after injury. The goal of this contract is to take the PoNS™ from an investigational medical device to an FDA-cleared device, obtaining clearance for the following indication: as an aid to therapy for chronic balance deficits resulting from mild to moderate traumatic brain injury (mTBI).

The Contractor will be the regulatory sponsor and overall project coordinator for the PoNS™ version 4.0 device. The critical components of this PWS to obtain FDA regulatory clearance include the following steps: (1) write the clinical study protocols, (2) execute the clinical studies, (3) manage the clinical research sites, (4) submit the *de novo*/510(k) or other application to FDA, and (5) gain FDA clearance of the PoNS^{TM} version 4.0 device for a mild-to-moderate TBI indication.

1.2. Scope:

This is a Research and Development (R&D) contract. The objective of this contract is to execute the clinical studies and regulatory responsibilities necessary to obtain FDA clearance for the PoNS™ 4.0 device and provide two FDA-cleared devices to the DoD (specifically USAMMA).

The Contractor shall complete the tasks noted in paragraph 3.1 to support the *de novo*/510(k) clearance application in accordance with (IAW) all noted applicable State, Federal, DoD, and U.S. Army regulations. The Contractor shall oversee and execute the clinical study. The Contractor shall support and perform services with DoD civilians, military and other Contractor personnel. The Contractor shall travel to Fort Detrick, Maryland at the Government's request for an annual In Progress Review (IPR).

1.2.1. The Contractor shall perform the services set forth in this PWS, pursuant to the award of a R&D contract. The Contractor shall furnish all management, personnel, services, and other items necessary to successfully deliver the required services. The Contractor shall possess knowledge and skills in PoNS^{TM} use/training/therapy, and regulatory requirements necessary to obtain 510(k) clearance.

1.2.2. This contract supports the Project Management Office, Medical Devices, and USAMMA. The Government shall not exercise any supervision or control over the Contractor's employees performing services under this contract. Contractor employees shall be accountable solely to the Contractor who, in turn is responsible to the Government.

1.2.3. The Contractor shall provide all personnel, equipment, supplies, facilities, transportation, tools, materials, supervision, and other items necessary to achieve the tasks as defined in this PWS.

1.2.4. Assumptions of the Parties:

1.2.4.1. A *de novo*/510 (k) petition shall be required for FDA to clear the PoNS™ 4.0 device.

1.2.4.2. The clinical trial using PoNS™ is considered to be of non-significant risk and, therefore, shall not require an Investigational Device Exemption submission.

1.2.4.3. QSR-produced PoNS™ 4.0 devices shall be available in/around April 2015 for use in the study. The devices shall be provided to the clinical trial sites by the Sponsor/Contractor.

1.2.4.4. The study shall take approximately 9-12 months to complete.

1.3. Period of Performance. The period of performance shall be for one (1) thirty (30) month Base Period. The Period of Performance breakdown reads as follows:

Base Period	01 July 2015 – 31 December 2017

2. General Requirements:

2.1. Business Relations:

The Contractor shall successfully integrate and coordinate all activity needed to execute the requirement. The Contractor shall manage the timeliness, completeness, and quality of problem identification. The Contractor shall provide corrective action plans, proposal submittals, timely identification of issues, and effective management of subcontractors. The Contractor shall seek to ensure customer satisfaction and professional and ethical behavior of all Contractor personnel.

2.2. Contract Administration and Management:

This PWS provides distinct activities and functions. These activities are described in the following subsections, which specify requirements for contract management, contract administration, and personnel administration.

2.2.1. Contract Management:

The Contractor shall establish clear organizational lines of authority and responsibility to ensure effective management of the resources assigned to the requirement.

2.2.1.1. Management Activities. The Contractor shall identify a single point of contact as the Project Manager (PM). The Contractor PM shall ensure that the task is performed efficiently, accurately, timely, and in compliance with this PWS. The Contractor PM shall coordinate, as necessary with the Contracting Officer Representative (COR), to ensure the services are managed consistently with overall contract requirements. The Contractor PM shall submit all invoices within 30 days from completion of tasks at the end of each month.

2.2.2. Contract Administration. The Contractor shall establish processes and assign appropriate resources to effectively administer this contract. The Contractor shall respond to Government requests for contractual actions within one (1) day. The Contractor shall have a single point of contact between the Government and Contractor employee assigned to support the contract.

2.3. Subcontract Management. The Contractor shall:

2.3.1. Manage any subcontract management necessary to integrate services to meet the overall requirements of this contract.

2.3.2. Be responsible and accountable for subcontractor performance on this requirement.

2.3.3. Manage work distribution to ensure there are no Organizational Conflict of Interest (OCI) considerations.

2.3.4. Add subcontractors to their team, as needed, after notification to the KO or COR. The Government may or may not permit cross-teaming (See paragraph 7.1.12 for definition).

2.4. Travel. The COR is designated, in writing, as the Contractor's travel order approval authority by the contracting officer. Travel to government facilities or other locations that are **requested by the Government** for the annual IPR may be required. Only travel requirements specifically **requested by the Government** (including plans, agenda, itinerary, or dates) shall be pre-approved by the COR and is on a strictly cost-reimbursable basis. Costs for travel shall be billed IAW the regulatory implementation of Public Law 99-234 and FAR 31.205 -46 *Travel Costs*.

2.5. Anti-terrorism / Operation Security. For Contract Requiring Performance or Delivery in a Foreign Country. DFARS Clause 252.225 -7043, *Antiterrorism/Force Protection for Defense Contractors Outside the United States.* The clause shall be used in solicitations and contracts that require performance or delivery in a foreign country. This clause applies to both contingencies and non-contingency support. The key AT requirement is for nonlocal national contractor personnel to comply with theater clearance requirements and allows the combatant commander to exercise oversight to ensure the contractor's compliance with combatant commander and subordinate task force commander policies and directives.

3. Specific Tasks and Performance Objectives

The Contractor shall complete development of the PoNS^{TM} device from its current state as an investigational device to a FDA cleared/approved medical device for the following indication: an aid to therapy for chronic balance deficits resulting from mild to moderate TBI. The Contractor shall be the FDA regulatory sponsor, in accordance with Section 21, Code of Federal Regulations. The Contractor shall deliver two complete FDA cleared/approved devices to the government. The Contractor shall accomplish all required tasks and services IAW this PWS that include, but are not limited to the following Specific Tasks and Performance Objectives for the contract.

3.1. Contract Tasks and Performance Objectives Required Before Start of Clinical Trial

3.1.1. Project Management Plan. The Contractor shall provide a draft Project Management Plan, including an initial Integrated Master Schedule (IMS) and Risk Management Plan that encompasses the entire scope of the contract, with the Contractor's proposal. The final Project Management Plan shall be submitted within 30 days of contract award. The IMS documents the critical path (including futility point), major milestones, tasks/activities, deliverables, duration, lead/lag/slack time and schedule relationships, and is directly traceable to the PWS. The IMS will contain all major project management tasks and associated milestones and/or deliverables to assist the Government in its monitoring of Contractor performance. The IMS shall be updated quarterly to track progress (CDRL A001 / QASP #1).

3.1.2. Quality Control Plan (QCP). The Contractor shall provide a draft QCP with the Contractor's proposal. The Contractor shall prepare and implement a final QCP to ensure that all activities of the project are managed in a sound, reasonable way in conformance to the Government's requirements within 30 days of contract award. The Contractor shall ensure that all deliverables produced are acceptable prior to delivery to the Government. Under this QCP, the Contractor shall provide for the Government or its designee to audit the Contractor and/or its Subcontractors for regulatory compliance and quality assurance purposes. At a minimum, the QCP shall include a self-inspection plan, an internal staffing plan, and an outline of the procedures that the Contractor shall use to maintain quality, timeliness, responsiveness and customer satisfaction. The QCP shall be updated as needed and reviewed at least quarterly (CDRL A002 / QASP #1).

3.1.3. Institutional Review Board Approved Clinical Protocols. The Contractor shall provide a copy of the IRB-approved clinical study protocol and informed consent form for each study site within 3 months of contract award. The Contractor shall also provide the COR supporting documentation that shall include at minimum a Statistical Analysis Plan, Clinical Monitoring Plan, Data Management Plan, Proposed Clinical Data Management System, Sample Case Report Forms, End User Guidelines (Training and Technical Support), and a Recruitment and Retention Plan for each site. The Contractor shall provide a copy of the IRB-approved clinical study protocol and informed consent form for any additional study site. The Contractor shall also provide the COR supporting documentation that shall include at minimum a Statistical Analysis Plan, Clinical Monitoring Plan, Data Management Plan, Proposed Clinical Data Management System, Sample Case Report Forms, End User Guidelines (Training and Technical Support), and a Recruitment and Retention Plan for any additional study site (CDRL A003 / QASP #2).

3.1.4. Institutional Review Board Approvals. The Contractor shall provide the COR with documentation of appropriate IRB approvals from each study site, institute, and Army, as required within 3 months of contract award and prior to the start of the clinical study. The Contractor shall provide the COR with documentation of appropriate IRB approvals from any additional study site, institute, and Army, as required. The Contractor shall maintain and update files of all applicable regulatory documentation for all appropriate IRBs (CDRL A004 / QASP #3).

3.1.5. Representative Test Articles. The Contractor shall provide final development and manufacturing of sufficient representative test articles (PoNS^{TM} version 4.0 device) for use in the clinical trial for a minimum of 120 subjects (and/or a proportionate amount consistent with FDA guidance), including a contingency plan for replacement of defective and/or test articles that may be lost or damaged during the clinical trial. The devices shall be manufactured in a Title 21 CFR §820 *Quality Systems Regulation (QSR)*-compliant manufacturing facility and process that has successfully completed design verification testing and human factors testing (CDRL A005 / QASP #4).

3.2. Contract Tasks and Performance Objectives Required During Clinical Trial:

3.2.1. Conduct Clinical Trial. The Contractor shall conduct a clinical study to evaluate the treatment effect on balance using the PoNS^{TM} version 4.0 devices at a minimum of three (3) study sites for a total of 120 subjects (and/or a proportionate amount consistent with FDA guidance). The Contractor shall conduct the clinical study in accordance with the study protocol and governing FDA Regulations. The Contractor shall provide a copy of their agreement with each study site that shall be responsible for executing the clinical trial in a manner that successfully supports an FDA submission and provide the COR with monthly status reports (CDRL A011 / QASP Item #1 and #5).

3.2.2. Interim Data Analysis. The Contractor shall conduct interim data analysis after 60 subjects (and/or a proportionate amount consistent with FDA guidance) to evaluate the observed treatment effect in order to determine if the study is adequately powered. The Contractor shall provide an Interim Clinical Study Report that includes the raw data and statistical analysis on the results within 30 day after completion of the 60 (or proportionate amount) subject testing , the futility point, and a mitigation plan for issues identified during the analysis (CDRL A007 / QASP #6).

3.3. Contract Tasks and Performance Objectives Required After Conclusion of Clinical Trial:

3.3.1. Final Clinical Study Report. The Contractor shall provide a complete Final Clinical Study Report that includes raw data and statistical analysis 75 days after completion of the study (CDRL 008 / QASP #1).

3.3.2. FDA Submission Packet. The Contractor shall provide data as deemed necessary by the FDA to support a clinical trial, and a copy of the *de novo*/510(k) application submission packet with copies of all supporting documentation, including but not limited to, the Pre-clinical Study results summary. This documentation shall be provided concurrent with FDA submission (CDRL A009 / QASP #7).

3.3.3. Final Report. The Contractor shall provide a Final Report that is formatted using best practices and consolidate (summarize) all data, costs, results, final status on all deliverables, and work activities performed during the contract period within 30 days after the end of the contract (CDRL A011 / QASP #1).

3.3.4. Technical Data Packet. The Contractor shall provide the COR with a complete technical data packet (TDP) upon request by the Government within seven (7) business days. The Contractor shall prepare and maintain currency of a TDP that includes all necessary documentation and technical data and reports collected and prepared during the development effort funded by the Government. The TDP shall include all necessary documentation and data for the Government, or its designee, to continue the development or production of the product, including but not limited to the Design History File, Device Master Record, and Device History File. The Contractor shall assist in the technical transfer as directed by the Government. The Contractor shall provide copies of TDP content as requested by Government and at contract expiration (CDRL A010 / QASP #8).

3.4. Contract Tasks and Performance Objectives Required After FDA Clearance/Approval:

3.4.1. FDA Cleared Devices. The Contractor shall provide two (2) FDA cleared the PoNS^{TM} devices with an indication as an aid to therapy for chronic balance deficits resulting from mild to moderate TBI, and all accessories, product inserts, and supporting manuals/literature (e.g., including user, technical, and maintenance manuals), as applicable, to the COR within 10 business days of FDA clearance (QASP #9). Any minor deviation of the above indication required by FDA guidance, must be approved by the Government and will be considered in scope of this contract.

3.5. Contract Tasks and Performance Objectives Required During Duration of Contract:

3.5.1. Progress, Status, and Management Reports. The Contractor shall provide annual, quarterly, and monthly Progress, Status, and Management Reports that describe progress made within the period, status of milestones and deliverables, cost expenditures against proposed costs (resource utilization), and inform the Government of existing or potential issues and problem areas and risk mitigation plans. The Contractor shall periodically provide an oral or email status report as the task proceeds to support the integrated product team needs for presentations and other tasks as needed to support the product effort. The reports shall include an updated IMS that shows the percent complete of each scheduled task item. Percent complete is defined as the cumulative amount of work actually performed through the end of the reporting month expressed as a percentage of the total amount of work to be performed. Monthly reports shall be provided to the COR the 10th day of each month, quarterly reports shall be provided the 15th day of each quarter, and annual reports shall be provided the 15th day after the end of each year (CDRL A011 / QASP #1).

3.5.2. Production or Delivery Problem Reports. Any significant positive or negative deviation to the schedule or scope of a task shall be explained and documented by the Contractor in its annual, quarterly, and monthly progress, and Status and Management Report shall be reported to the Government within 2 weeks of identification as a Production or Delivery Problem Report (CDRL A011 / QASP #1).

3.5.3. Annual Program Reviews. The Contractor shall formally present the prior year's progress as part of an annual program review (for example, the IPR). The content of the briefing shall include but not be limited to the following: completed tasks within the year, highlights of completed tasks, summary of results from in-process studies, schedule updates, summary of results from completed studies, risks/issues, and funding execution. The annual program reviews shall be held at Fort Detrick, MD and may be held in conjunction with the integrated product team (IPT) meetings with senior leadership. Additional requests for travel to Fort Detrick, MD may be requested by the Government as needed (CDRL A011 / QASP #1).

3.5.4. FDA Communication and Study Reports. The Contractor shall provide the COR with FDA Communication and Study Reports. Regulatory documents including informal emails sent to the FDA are sent concurrently to the Government. Meeting notes shall be sent to the Government if efforts to attend verbal meetings (such as phone calls or meetings at the FDA) are not possible. Copies of informal and formal regulatory communications received from the FDA shall be sent within three (3) business days of receipt. Copies of Clinical Monitoring Reports should be sent within 30 business days of receipt (CDRL A013 / QASP #7).

3.5.5. Trip Reports. The Contractor shall provide Trip Reports within five (5) business days for trips that have been requested by the Government. The report should describe the purpose, results of the trip, and actual costs (CDRL A001 / QASP #1).

3.5.6. The Contractor shall assist in Kick-Off, coordination, progress update, and informational meetings.

3.5.7. The Contractor shall provide guidance and consult with Principal Investigator, senior staff, and clinical personnel during formal training and to review data from pilot trial. The Contractor shall provide recommendations for modifications to interventions when used with the PoNS^{TM} device, measurement tools and procedures.

3.5.8. The Contractor shall consult on data interpretation and collaborate on publications and presentations.

4. Deliverables:

The Contractor shall provide deliverables as described in the below chart.

Deliverable Table

Item	PWS Ref	Title	Distribution	E	Initial & Subsequent
1	2.2.1.1.	Program Manager Point of Contact	COR	1	Upon award of contract
2	3.1.1.	Final Project Management Plan (A001)	COR	1	Within 30 Calendar days after contract award; update quarterly
3	3.1.1.	Final Integrated Master Schedule (CDRL A001)	COR	1	Within 30 Calendar days after contract award; update quarterly
4	3.1.1.	Risk Management Plan (CDRL A001)	COR	1	Within 30 Calendar days after contract award; updated quarterly
5	3.1.2.	Quality Control Plan (CDRL A002)	COR	1	Within 30 Calendar days after contract award; update as needed; review quarterly
6	3.1.3.	IRB-approved Clinical Protocol for each Study Site (CDRL A003)	COR	1	Within 3 months of award of contract and when additional sites are added.
7	3.1.3.	Statistical Analysis Plan (CDRL A003)	COR	1	Within 3 months of award of contract and when additional sites are added.
8	3.1.3.	Clinical Monitoring Plan (CDRL A003)	COR	1	Within 3 months of award of contract and when additional sites are added.
9	3.1.3.	Data Management Plan (CDRL A003)	COR	1	Within 3 months of award of contract and when additional sites are added.
10	3.1.3.	Proposed Clinical Data Management System (CDRL A003)	COR	1	Within 3 months of award of contract and when additional sites are added.
11	3.1.3.	Sample Case Report Forms (CDRL A003)	COR	1	Within 3 months of award of contract and when additional sites are added.
12	3.1.3.	End User Guidelines (CDRL A003)	COR	1	Within 3 months of award of contract and when additional sites are added.
13	3.1.3.	Recruitment and Retention Plan for each Clinical Site (CDRL A003)	COR	1	Within 3 months of award of contract and when additional sites are added.
14	3.1.4.	IRB Approvals (CDRL A004)	COR	1	Within 3 months of award of contract and prior to start of clinical trial and when additional sites are added.
15	3.1.5.	Representative Test Articles (sent to	COR	1	Prior to start of clinical trial

Item	PWS Ref	Title	Distribution	E	Initial & Subsequent
		study sites) (CDRL A005)			
16	3.1.5.	Contingency Manufacturing Plan (CDRL A005)	COR	1	Prior to start of clinical trial
17	3.2.1.	Conduct Clinical Trial (CDRL A006)	COR	1	Copy of agreement with each study site prior to the start of the trial; monthly status report
18	3.2.2.	Interim Clinical Study Report & Mitigation Plan (CDRL A007)	COR		Within 30 days of completion of n = 60 subjects (and/or a proportionate amount consistent with FDA guidance)
19	3.3.1.	Final Clinical Study Report (CDRL A008)	COR	1	Within 75 days after completion of study
20	3.3.2.	FDA Submission Packet (CDRL A009)	COR	1	Concurrently with FDA submission
21	3.3.3.	Final Report	COR	1	Within 30 days after end of contract
22	3.3.4.	Technical Data Packet (CDRL A010)	COR	1	Seven (7) business days upon request and final TDP at end of contract
23	3.4.1.	FDA cleared PoNS^{TM} Devices	COR	N A	Within 10 business days of FDA clearance (2 devices)
24	3.5.1.	Monthly Progress, Status, and Management Reports (CDRL A011)	COR	1	Monthly reports due the 10th day of each month.
25	3.5.1.	Quarterly Progress, Status, and Management Reports (CDRL A011)	COR	1	Quarterly reports due the 15th day after end of each quarter.
26	3.5.1.	Annual Progress, Status, and Management Reports (CDRL A011)	COR		Annual reports due the 15th day after end of each year
27	3.5.2.	Production or Delivery Problem Reports (CDRL A012)	COR	1	Within 2 weeks of identification of deviation to schedule or scope of any task as needed
28	3.5.3.	Annual Program Reviews	IPT	N A	Annually In Process Review at Fort Detrick, MD
29	3.5.4.	FDA Communication and Study Reports (CDRL A013)	COR	1	Concurrently and/or 3 business days as applicable (see PWS 3.1.18.)
30	3.5.5.	Trip Reports	COR	1	Within 5 business days for Government requested travel

5. List of Acronyms:

AMEDD	Army Medical Department
CFR	Code of Federal Regulations
CONUS	Continental United States (excludes Alaska and Hawaii)
COR	Contracting Officer Representative
CRO	Clinical Research Organization
DD250	Department of Defense Form 250 (Receiving Report)
DD254	Department of Defense Contract Security Requirement List
DFARS	Defense Federal Acquisition Regulation Supplement
DoD	Department of Defense
FAR	Federal Acquisition Regulation
FDA	United States Food and Drug Administration
HIPAA	Health Insurance Portability and Accountability Act of 1996
IAW	In Accordance With
IMS	Integrated Master Schedule
IRB	Institutional Review Board
KO	Contracting Officer
n	Number of Research Subjects
NA	Not Applicable
NDA	Non-disclosure Agreement
NHC	NeuroHabilitation Corporation
OCI	Organizational Conflict of Interest
OCONUS	Outside Continental United States (includes Alaska and Hawaii)
ODC	Other Direct Costs
PM	Project Manager
PoNS™	Portable Neuromodulation Stimulator
PWS	Performance Work Statement
QA	Quality Assurance
QAP	Quality Assurance Program
QASP	Quality QAP Assurance Surveillance Plan
QC	Quality Control
QCP	Quality Control Plan
QSR	Quality Systems Regulations
TDP	Technical Data Packet
TBI	Traumatic Brain Injury
USAMMA	United States Army Medical Materiel Agency
USAMRMC	United States Medical Research and Materiel Command

SECTION F - DELIVERIES OR PERFORMANCE

The following Delivery Schedule item for CLIN 0001 has been changed from:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC
POP 01-JUL-2015 TO 31-DEC-2016	N/A	US ARMY MEDICAL MATERIEL AGENCY W25MWY US ARMY MEDICAL MATERIEL AGENCY 693 NEIMAN STREET FREDERICK MD 21702 301-619-4518 FOB: Destination	

To:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC
POP 01-JUL-2015 TO 31-DEC-2017	N/A	US ARMY MEDICAL MATERIEL AGENCY W25MWY US ARMY MEDICAL MATERIEL AGENCY 693 NEIMAN STREET FREDERICK MD 21702 301-619-4518 FOB: Destination	

The following Delivery Schedule item for CLIN 0002 has been changed from:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC
POP 01-JUL-2015 TO 30-DEC-2016	N/A	US ARMY MEDICAL MATERIEL AGENCY W25MWY US ARMY MEDICAL MATERIEL AGENCY 693 NEIMAN STREET FREDERICK MD 21702 301-619-4518 FOB: Destination	

To:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC
POP 01-JUL-2015 TO 31-DEC-2017	N/A	US ARMY MEDICAL MATERIEL AGENCY W25MWY US ARMY MEDICAL MATERIEL AGENCY 693 NEIMAN STREET FREDERICK MD 21702 301-619-4518 FOB: Destination	

The following Delivery Schedule item for CLIN 0003 has been changed from:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC
POP 01-JUL-2015 TO 30-DEC-2016	N/A	US ARMY MEDICAL MATERIEL AGENCY W25MWY US ARMY MEDICAL MATERIEL AGENCY 693 NEIMAN STREET FREDERICK MD 21702 301-619-4518 FOB: Destination	

To:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC

POP 01-JUL-2015 TO 31-DEC-2017	N/A	US ARMY MEDICAL MATERIEL AGENCY W25MWY US ARMY MEDICAL MATERIEL AGENCY 693 NEIMAN STREET FREDERICK MD 21702 301-619-4518 FOB: Destination

SECTION G - CONTRACT ADMINISTRATION DATA

The following have been added by full text:

MODIFIED PAYMENT SCHEDULE

Modified Payment Schedule for subject completion and delivery of two (2) FDA cleared devices. CLIN 0003 – Other Direct Costs (ODCs) for travel expenses is excluded from this modified payment schedule.

Payment 1: The NeuroHabilitation Corporation (NHC) may invoice CLIN 0001 for $2,807.49 and CLIN 0002 for $229,795.42 upon the completion of 30 subjects.

Payment 2: NHC may invoice CLIN 0001 for $2,807.49 and CLIN 0002 for $229,795.42 upon the completion of 60 subjects.

Payment 3: NHC may invoice CLIN 0001 for $2,807.49 and CLIN 0002 for $229,795.42 upon the completion of 90 subjects.

Payment 4: NHC may invoice CLIN 0001 for $2,807.49 and CLIN 0002 for $229,795.42 upon the completion of 120 subjects.

Payment 5: NHC may invoice CLIN 0001 for $2,807.52 and CLIN 0002 for $229,795.43 once two (2) FDA cleared devices are delivered to the U.S. Army Medical Materiel Agency (USAMMA).

The following have been modified:

252.232 -7006 WIDE AREA WORKFLOW PAYMENT INSTRUCTIONS (MAY 2013)

(a) Definitions. As used in this clause--

Department of Defense Activity Address Code (DoDAAC) is a six position code that uniquely identifies a unit, activity, or organization.

Document type means the type of payment request or receiving report available for creation in Wide Area WorkFlow (WAWF).

Local processing office (LPO) is the office responsible for payment certification when payment certification is done external to the entitlement system.

(b) Electronic invoicing. The WAWF system is the method to electronically process vendor payment requests and receiving reports, as authorized by DFARS 252.232 -7003, Electronic Submission of Payment Requests and Receiving Reports.

(c) WAWF access. To access WAWF, the Contractor shall--

(1) Have a designated electronic business point of contact in the System for Award Management at https://www.acquisition.gov; and

(2) Be registered to use WAWF at https://wawf.eb.mil/ following the step-by-step procedures for self-registration available at this Web site.

(d) WAWF training. The Contractor should follow the training instructions of the WAWF Web-Based Training Course and use the Practice Training Site before submitting payment requests through WAWF. Both can be accessed by selecting the “Web Based Training” link on the WAWF home page at https://wawf.eb.mil/.

(e) WAWF methods of document submission. Document submissions may be via Web entry, Electronic Data Interchange, or File Transfer Protocol.

(f) WAWF payment instructions. The Contractor must use the following information when submitting payment requests and receiving reports in WAWF for this contract/order:

(1) Document type. The Contractor shall use the following document type(s).

Invoice 2-in-1 Services (Services Only)

(2) Inspection/acceptance location. The Contractor shall select the following inspection/acceptance location(s) in WAWF, as specified by the contracting officer.

Not Applicable

(3) Document routing. The Contractor shall use the information in the Routing Data Table below only to fill in applicable fields in WAWF when creating payment requests and receiving reports in the system.

Routing Data Table*

Field Name in WAWF	Data to be entered in WAWF
Pay Official DoDAAC	HQ0490
Issue By DoDAAC	W81XWH
Admin DoDAAC	W81XWH
Inspect By DoDAAC	W25MWY
Ship To Code	W25MWY
Ship From Code	_____
Mark For Code	_____
Service Approver (DoDAAC)	HAA391
Service Acceptor (DoDAAC)	HAA391
Accept at Other DoDAAC	N/A
LPO DoDAAC	N/A
DCAA Auditor DoDAAC	HAA391
Other DoDAAC(s)	N/A

(4) Payment request and supporting documentation. The Contractor shall ensure a payment request includes appropriate contract line item and subline item descriptions of the work performed or supplies delivered, unit price/cost per unit, fee (if applicable), and all relevant back-up documentation, as defined in DFARS Appendix F, (e.g. timesheets) in support of each payment request.

(5) WAWF email notifications. The Contractor shall enter the email address identified below in the “Send Additional Email Notifications” field of WAWF once a document is submitted in the system.

Brian.i.dacanay.civ@mail.mil

(g) WAWF point of contact. (1) The Contractor may obtain clarification regarding invoicing in WAWF from the following contracting activity's WAWF point of contact.

Brian.i.dacanay.civ@mail.mil

(2) For technical WAWF help, contact the WAWF helpdesk at 866-618-5988.

(End of clause)

(End of Summary of Changes)

SOLICITATION, OFFER AND AWARD

1. THIS CONTRACT IS A RATED ORDER UNDER DPAS (15 CFR 700)	RATING	PAGE 1 OF PAGES 41

2. CONTRACT NO.	3. SOLICITATION NO.	4. TYPE OF SOLICITATION	5. DATE ISSUED	6. REQUISITION/PURCHASE NO.
W81XWH-15-C-0096	W81XWH-15-R-0023	[ ] SEALED BID (IFB) [X] NEGOTIATED (RFP)	27 Mar 2015	SEE SCHEDULE

7. ISSUED BY	CODE	8. ADDRESS OFFER TO (If other than Item 7)	CODE
USA MED RESEARCH ACQ ACTIVITY 820 CHANDLER ST FORT DETRICK MD 21702-5014 TEL: FAX:	W81XWH	See Item 7 TEL: FAX:	

NOTE: In sealed bid solicitations "offer" and "offeror" mean "bid" and "bidder".

SOLICITATION

9. Sealed offers in original and _____ copies for furnishing the supplies or services in the Schedule will be received at the place specified in Item 8, or if handcarried, in the depository located in _____ until _____ (Hour) local time _____ (Date)

CAUTION - LATE Submissions, Modifications, and Withdrawals: See Section L, Provision No. 52.214-7 or 52.215-1. All offers are subject to all terms and conditions contained in this solicitation.

10. FOR INFORMATION CALL:	A. NAME	B. TELEPHONE (Include area code) (NO COLLECT CALLS)	C. E-MAIL ADDRESS
	CHRISTOPHER SULT	301-619-1342	christopher.m.sult.civ@mail.mil

11. TABLE OF CONTENTS

(X)	SEC.	DESCRIPTION	PAGE(S)	(X)	SEC.	DESCRIPTION	PAGE(S)
		PART I - THE SCHEDULE				**PART II - CONTRACT CLAUSES**	
X	A	SOLICITATION/ CONTRACT FORM	1 - 2	X	I	CONTRACT CLAUSES	23 - 40
X	B	SUPPLIES OR SERVICES AND PRICES/ COSTS	3 - 4			**PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS**	
X	C	DESCRIPTION/ SPECS./ WORK STATEMENT	5 - 13	X	J	LIST OF ATTACHMENTS	41
	D	PACKAGING AND MARKING				**PART IV - REPRESENTATIONS AND INSTRUCTIONS**	
X	E	INSPECTION AND ACCEPTANCE	14		K	REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS	
X	F	DELIVERIES OR PERFORMANCE	15				
X	G	CONTRACT ADMINISTRATION DATA	16 - 18		L	INSTRS., CONDS., AND NOTICES TO OFFERORS	
X	H	SPECIAL CONTRACT REQUIREMENTS	19 - 22		M	EVALUATION FACTORS FOR AWARD	

OFFER (Must be fully completed by offeror)

NOTE: Item 12 does not apply if the solicitation includes the provisions at 52.214-16, Minimum Bid Acceptance Period.

12. In compliance with the above, the undersigned agrees, if this offer is accepted within _____ calendar days (60 calendar days unless a different period is inserted by the offeror) from the date for receipt of offers specified above, to furnish any or all items upon which prices are offered at the price set opposite each item, delivered at the designated point(s), within the time specified in the schedule.

13. DISCOUNT FOR PROMPT PAYMENT (See Section I, Clause No. 52.232-8)	

14. ACKNOWLEDGMENT OF AMENDMENTS (The offeror acknowledges receipt of amendments to the SOLICITATION for offerors and related documents numbered and dated):	AMENDMENT NO.	DATE	AMENDMENT NO.	DATE

15A. NAME AND ADDRESS OF OFFEROR	CODE 7BGE6	FACILITY	16. NAME AND TITLE OF PERSON AUTHORIZED TO SIGN OFFER (Type or print)
	NEUROHABILITATION CORPORATION 41 UNIVERSITY DR STE 400 NEWTOWN PA 18940-1873		

15B. TELEPHONE NO (Include area code)	15C. CHECK IF REMITTANCE ADDRESS IS DIFFERENT FROM ABOVE - ENTER SUCH ADDRESS IN SCHEDULE.	17. SIGNATURE	18. OFFER DATE
	☐		

AWARD (To be completed by Government)

19. ACCEPTED AS TO ITEMS NUMBERED	20. AMOUNT	21. ACCOUNTING AND APPROPRIATION
	$2,996,244.00	See Schedule

22. AUTHORITY FOR USING OTHER THAN FULL AND OPEN COMPETITION:	23. SUBMIT INVOICES TO ADDRESS SHOWN IN (4 copies unless otherwise specified) 1	ITEM
☐ 10 U.S.C. 2304(c)( ) ☐ 41 U.S.C. 253(c)( )		Section G

24. ADMINISTERED BY (If other than Item 7)	CODE	25. PAYMENT WILL BE MADE BY	CODE HQ0490
See Item 7		DEFENSE FINANCE AND ACCOUNTING SERVICE DFAS-INDY VP GFEBS 8899 E 56TH STREET INDIANAPOLIS IN 46249-3800	

26. NAME OF CONTRACTING OFFICER (Type or print)	27. UNITED STATES OF AMERICA	28. AWARD DATE
BARRY G. SAYER TEL: (301) 619-2375 EMAIL: barry.g.sayer.civ@mail.mil	(Signature of Contracting Officer)	01-Jul-2015

IMPORTANT - Award will be made on this Form, or on Standard Form 26, or by other authorized official written notice.

Section A - Solicitation/Contract Form

ADDITIONAL INFORMATION
ADDITIONAL INFORMATION

PROJECT TITLE: Development and U.S. Food and Drug Administration (FDA) Clearance of the Portable Neuromodulation Stimulator (PoNS) Device.

The requirement is an R&D contract.

GOVERNMENT POINTS OF CONTACT

The Contract Specialist for this contract is Chris Sult at USAMRAA, ATTN: Chris Sult, MRMC-AAA-SD, 820 Chandler Street, Fort Detrick, MD 21702-5014 or christopher.m.sult.civ@mail.mil or 301-619-1342.

The Contracting Officer for this contract is Barry Sayer at USAMRAA, ATTN: Barry Sayer, MRMC-AAA-SD, 820 Chandler Street, Fort Detrick, MD 21702-5014 or barry.g.sayer.civ@mail.mil or 301-619-2375.

The Contracting Officer's Representative for this contract is Scott Colmyer at USAMMA, ATTN: Scott Colmyer, 693 Neiman Street, Fort Detrick, MD 21702 or scott.d.colmyer.civ@mail.mil or 301-619-6982.

Section B - Supplies or Services and Prices

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0001		1	Job		$217,975.21
	Labor - Sponsor				
	COST				
	Labor - Sponsor, Development and FDA Clearance of the PoNS device.				
	FOB: Destination				
	PURCHASE REQUEST NUMBER: 0010553630-0003				
				ESTIMATED COST	$217,975.21NTE
	ACRN AA				$217,975.21
	CIN: GFEBS001055363000001				

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0002		1	Job		$2,763,289.24
	ODC - Subcontractor Expenses				
	COST				
	Other Direct Costs (ODCs) - Subcontractor expenses to include; Clinical				
	Research Organization, Regulatory, Contract Manufacturing, and Consultant.				
	FOB: Destination				
	PURCHASE REQUEST NUMBER: 0010553630-0002				
				ESTIMATED COST	$2,763,289.24NTE
	ACRN AA				$2,763,289.24
	CIN: GFEBS001055363000002				

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0003		1	Job		$14,979.55
	ODC - Travel				
	COST				
	Other Direct Costs (ODCs) - Travel				
	FOB: Destination				
	PURCHASE REQUEST NUMBER: 0010553630-0002				
				ESTIMATED COST	$14,979.55NTE
	ACRN AA				$14,979.55
	CIN: GFEBS001055363000003				

Section C - Descriptions and Specifications

PERFORMANCE WORK STATEMENT

PERFORMANCE WORK STATEMENT (PWS)

Development and U.S. Food and Drug Administration (FDA) Clearance of the Portable Neuromodulation Stimulator (PoNS™) Device

1. Introduction:

The U.S. Amy Medical Materiel Agency (USAMMA) and its parent organization the U.S. Army Medical Research and Materiel Command (USAMRMC) are located at Fort Detrick, in Frederick, Maryland. USAMMA serves as the strategic level, medical logistics generating force, and medical lifecycle management command in support of Army Medicine, the Army Campaign Plan, Military Health System, and Combatant Commands. The agency provides optimal medical acquisition and logistics support and solutions across the full spectrum of military health care missions worldwide. USAMMA has operational oversight of medical materiel acquisition programs and serves as the Army Medical Department's (AMEDD's) command for fielding new medical materiel for the Army's operational forces.

1.1. Background and Purpose:

The U.S. Army is supporting an effort to develop NeuroHabilitation Corporation's (NHC) Portable Neuromodulation Stimulator (PoNS™) as an aid to therapy for chronic balance deficits resulting from a mild to moderate traumatic brain injury (TBI). On 1 February 2013, USAMMA, the U.S. Army Medical Materiel Development Activity (USAMMDA), and NHC established a collaborative relationship, via a Cooperative Research and Development Agreement (CRADA) under 15 USC §3710a, to develop an investigational medical device that employs non-invasive brain stimulation. The PoNS™ device, developed partially under the CRADA, works by applying principles of neuroplasticity that enables the brain to process information in new ways for rehabilitation after injury. The goal of this contract is to take the PoNS™ from an investigational medical device to an FDA-cleared device, obtaining clearance for the following indication: as an aid to therapy for chronic balance deficits resulting from mild to moderate traumatic brain injury (TBI).

The Contractor will be the regulatory sponsor and overall project coordinator for the PoNS™ version 4.0 device. The critical components of this PWS to obtain FDA regulatory clearance include the following steps: (1) write the clinical study protocols, (2) execute the clinical studies, (3) manage the clinical research sites, (4) submit the *de novo*/510(k) or other application to FDA, and (5) gain FDA clearance of the PoNS^{TM} version 4.0 device for a mild-to-moderate TBI indication.

1.2. Scope:

This is a Research and Development (R&D) contract. The objective of this contract is to execute the clinical studies and regulatory responsibilities necessary to obtain FDA clearance for the PoNS™ 4.0 device and provide two FDA-cleared devices to the DoD (specifically USAMMA).

The Contractor shall complete the tasks noted in paragraph 3.1 to support the *de novo*/510(k) clearance application in accordance with (IAW) all noted applicable State, Federal, DoD, and U.S. Army regulations. The Contractor shall oversee and execute the clinical study. The Contractor shall support and perform services with DoD civilians, military and other Contractor personnel. The Contractor shall travel to Fort Detrick, Maryland at the Government's request for an annual In Progress Review (IPR).

1.2.1. The Contractor shall perform the services set forth in this PWS, pursuant to the award of a R&D contract. The Contractor shall furnish all management, personnel, services, and other items necessary to successfully deliver the required services. The Contractor shall possess knowledge and skills in PoNS^{TM} use/training/therapy, and regulatory requirements necessary to obtain 510(k) clearance.

1.2.2. This contract supports the Project Management Office, Medical Devices, and USAMMA. The Government shall not exercise any supervision or control over the Contractor's employees performing services under this contract. Contractor employees shall be accountable solely to the Contractor who, in turn is responsible to the Government.

1.2.3. The Contractor shall provide all personnel, equipment, supplies, facilities, transportation, tools, materials, supervision, and other items necessary to achieve the tasks as defined in this PWS.

1.2.4. Assumptions of the Parties:

1.2.4.1. A *de novo/*510 (k) petition shall be required for FDA to clear the PoNS™ 4.0 device.

1.2.4.2. The clinical trial using PoNS™ is considered to be of non-significant risk and, therefore, shall not require an Investigational Device Exemption submission.

1.2.4.3. QSR-produced PoNS™ 4.0 devices shall be available in/around April 2015 for use in the study. The devices shall be provided to the clinical trial sites by the Sponsor/Contractor.

1.2.4.4. The study shall take approximately 9-12 months to complete.

1.3. Period of Performance. The period of performance shall be for one (1) eighteen (18) month Base Period. The Period of Performance breakdown reads as follows:

Base Period	01 July 2015 – 31 December 2016

2. General Requirements:

2.1. Business Relations:

The Contractor shall successfully integrate and coordinate all activity needed to execute the requirement. The Contractor shall manage the timeliness, completeness, and quality of problem identification. The Contractor shall provide corrective action plans, proposal submittals, timely identification of issues, and effective management of subcontractors. The Contractor shall seek to ensure customer satisfaction and professional and ethical behavior of all Contractor personnel.

2.2. Contract Administration and Management:

This PWS provides distinct activities and functions. These activities are described in the following subsections, which specify requirements for contract management, contract administration, and personnel administration.

2.2.1. Contract Management:

The Contractor shall establish clear organizational lines of authority and responsibility to ensure effective management of the resources assigned to the requirement.

2.2.1.1. Management Activities. The Contractor shall identify a single point of contact as the Project Manager (PM). The Contractor PM shall ensure that the task is performed efficiently, accurately, timely, and in compliance with this PWS. The Contractor PM shall coordinate, as necessary with the Contracting Officer Representative (COR), to ensure the services are managed consistently with overall contract requirements. The Contractor PM shall submit all invoices within 30 days from completion of tasks at the end of each month.

2.2.2. Contract Administration. The Contractor shall establish processes and assign appropriate resources to effectively administer this contract. The Contractor shall respond to Government requests for contractual actions within one (1) day. The Contractor shall have a single point of contact between the Government and Contractor employee assigned to support the contract.

2.3. Subcontract Management. The Contractor shall:

2.3.1. Manage any subcontract management necessary to integrate services to meet the overall requirements of this contract.

2.3.2. Be responsible and accountable for subcontractor performance on this requirement.

2.3.3. Manage work distribution to ensure there are no Organizational Conflict of Interest (OCI) considerations.

2.3.4. Add subcontractors to their team, as needed, after notification to the KO or COR. The Government may or may not permit cross-teaming (See paragraph 7.1.12 for definition).

2.4. Travel. The COR is designated, in writing, as the Contractor's travel order approval authority by the contracting officer. Travel to government facilities or other locations that are **requested by the Government** for the annual IPR may be required. Only travel requirements specifically **requested by the Government** (including plans, agenda, itinerary, or dates) shall be pre-approved by the COR and is on a strictly cost-reimbursable basis. Costs for travel shall be billed IAW the regulatory implementation of Public Law 99-234 and FAR 31.205 -46 *Travel Costs*.

2.5. Anti-terrorism / Operation Security. For Contract Requiring Performance or Delivery in a Foreign Country. DFARS Clause 252.225 -7043, *Antiterrorism/Force Protection for Defense Contractors Outside the United States.*

The clause shall be used in solicitations and contracts that require performance or delivery in a foreign country. This clause applies to both contingencies and non-contingency support. The key AT requirement is for nonlocal national contractor personnel to comply with theater clearance requirements and allows the combatant commander to exercise oversight to ensure the contractor's compliance with combatant commander and subordinate task force commander policies and directives.

3. Specific Tasks and Performance Objectives

The Contractor shall complete development of the PoNS^{TM} device from its current state as an investigational device to a FDA cleared/approved medical device for the following indication: an aid to therapy for chronic balance deficits resulting from mild to moderate TBI. The Contractor shall be the FDA regulatory sponsor, in accordance with Section 21, Code of Federal Regulations. The Contractor shall deliver two complete FDA cleared/approved devices to the government. The Contractor shall accomplish all required tasks and services IAW this PWS that include, but are not limited to the following Specific Tasks and Performance Objectives for the contract.

3.1. Contract Tasks and Performance Objectives Required Before Start of Clinical Trial

3.1.1. Project Management Plan. The Contractor shall provide a draft Project Management Plan, including an initial Integrated Master Schedule (IMS) and Risk Management Plan that encompasses the entire scope of the contract, with the Contractor's proposal. The final Project Management Plan shall be submitted within 30 days of contract award. The IMS documents the critical path (including futility point), major milestones, tasks/activities, deliverables, duration, lead/lag/slack time and schedule relationships, and is directly traceable to the PWS. The IMS will contain all major project management tasks and associated milestones and/or deliverables to assist the Government in its monitoring of Contractor performance. The IMS shall be updated quarterly to track progress (CDRL A001 / QASP #1).

3.1.2. Quality Control Plan (QCP). The Contractor shall provide a draft QCP with the Contractor's proposal. The Contractor shall prepare and implement a final QCP to ensure that all activities of the project are managed in a sound, reasonable way in conformance to the Government's requirements within 30 days of contract award. The Contractor shall ensure that all deliverables produced are acceptable prior to delivery to the Government. Under this QCP, the Contractor shall provide for the Government or its designee to audit the Contractor and/or its Subcontractors for regulatory compliance and quality assurance purposes. At a minimum, the QCP shall include a self-inspection plan, an internal staffing plan, and an outline of the procedures that the Contractor shall use to maintain quality, timeliness, responsiveness and customer satisfaction. The QCP shall be updated as needed and reviewed at least quarterly (CDRL A002 / QASP #1).

3.1.3. Institutional Review Board Approved Clinical Protocols. The Contractor shall provide a copy of the IRB-approved clinical study protocol and informed consent form for each study site within 3 months of contract award. The Contractor shall also provide the COR supporting documentation that shall include at minimum a Statistical Analysis Plan, Clinical Monitoring Plan, Data Management Plan, Proposed Clinical Data Management System, Sample Case Report Forms, End User Guidelines (Training and Technical Support), and a Recruitment and Retention Plan for each site (CDRL A003 / QASP #2).

3.1.4. Institutional Review Board Approvals. The Contractor shall provide the COR with documentation of appropriate IRB approvals from each study site, institute, and Army, as required within 3 months of contract award and prior to the start of the clinical study. The Contractor shall maintain and update files of all applicable regulatory documentation for all appropriate IRBs (CDRL A004 / QASP #3).

3.1.5. Representative Test Articles. The Contractor shall provide final development and manufacturing of sufficient representative test articles (PoNS^{TM} version 4.0 device) for use in the clinical trial for a minimum of 120 subjects (and/or a proportionate amount consistent with FDA guidance), including a contingency plan for replacement of defective and/or test articles that may be lost or damaged during the clinical trial. The devices shall be manufactured in a Title 21 CFR §820 *Quality Systems Regulation (QSR)*-compliant manufacturing facility and process that has successfully completed design verification testing and human factors testing (CDRL A005 / QASP #4).

3.2. Contract Tasks and Performance Objectives Required During Clinical Trial:

3.2.1. Conduct Clinical Trial. The Contractor shall conduct a clinical study to evaluate the treatment effect on balance using the PoNS^{TM} version 4.0 devices at a minimum of three (3) study sites for a total of 120 subjects (and/or a proportionate amount consistent with FDA guidance). The Contractor shall conduct the clinical study in accordance with the study protocol and governing FDA Regulations. The Contractor shall provide a copy of their agreement with each study site that shall be responsible for executing the clinical trial in a manner that successfully supports an FDA submission and provide the COR with monthly status reports (CDRL A011 / QASP Item #1 and #5).

3.2.2. Interim Data Analysis. The Contractor shall conduct interim data analysis after 60 subjects (and/or a proportionate amount consistent with FDA guidance) to evaluate the observed treatment effect in order to determine if the study is adequately powered. The Contractor shall provide an Interim Clinical Study Report that includes the raw data and statistical analysis on the results within 30 day after completion of the 60 (or proportionate amount) subject testing , the futility point, and a mitigation plan for issues identified during the analysis (CDRL A007 / QASP #6).

3.3. Contract Tasks and Performance Objectives Required After Conclusion of Clinical Trial:

3.3.1. Final Clinical Study Report. The Contractor shall provide a complete Final Clinical Study Report that includes raw data and statistical analysis 75 days after completion of the study (CDRL 008 / QASP #1).

3.3.2. FDA Submission Packet. The Contractor shall provide data as deemed necessary by the FDA to support a clinical trial, and a copy of the *de novo*/510(k) application submission packet with copies of all supporting documentation, including but not limited to, the Pre-clinical Study results summary. This documentation shall be provided concurrent with FDA submission (CDRL A009 / QASP #7).

3.3.3. Final Report. The Contractor shall provide a Final Report that is formatted using best practices and consolidate (summarize) all data, costs, results, final status on all deliverables, and work activities performed during the contract period within 30 days after the end of the contract (CDRL A011 / QASP #1).

3.3.4. Technical Data Packet. The Contractor shall provide the COR with a complete technical data packet (TDP) upon request by the Government within seven (7) business days. The Contractor shall prepare and maintain currency of a TDP that includes all necessary documentation and technical data and reports collected and prepared during the development effort funded by the Government. The TDP shall include all necessary documentation and data for the Government, or its designee, to continue the development or production of the product, including but not limited to the Design History File, Device Master Record, and Device History File. The Contractor shall assist in the technical transfer as directed by the Government. The Contractor shall provide copies of TDP content as requested by Government and at contract expiration (CDRL A010 / QASP #8).

3.4. Contract Tasks and Performance Objectives Required After FDA Clearance/Approval:

3.4.1. FDA Cleared Devices. The Contractor shall provide two (2) FDA cleared the PoNS^{TM} devices with an indication as an aid to therapy for chronic balance deficits resulting from mild to moderate TBI, and all accessories, product inserts, and supporting manuals/literature (e.g., including user, technical, and maintenance manuals), as applicable, to the COR within 10 business days of FDA clearance (QASP #9). Any minor deviation of the above indication required by FDA guidance, must be approved by the Government and will be considered in scope of this contract.

3.5. Contract Tasks and Performance Objectives Required During Duration of Contract:

3.5.1. Progress, Status, and Management Reports. The Contractor shall provide annual, quarterly, and monthly Progress, Status, and Management Reports that describe progress made within the period, status of milestones and deliverables, cost expenditures against proposed costs (resource utilization), and inform the Government of existing or potential issues and problem areas and risk mitigation plans. The Contractor shall periodically provide an oral or email status report as the task proceeds to support the integrated product team needs for presentations and other tasks as needed to support the product effort. The reports shall include an updated IMS that shows the percent complete of each scheduled task item. Percent complete is defined as the cumulative amount of work actually performed through the end of the reporting month expressed as a percentage of the total amount of work to be performed. Monthly reports shall be provided to the COR the 10th day of each month, quarterly reports shall be provided the 15th day of each quarter, and annual reports shall be provided the 15th day after the end of each year (CDRL A011 / QASP #1).

3.5.2. Production or Delivery Problem Reports. Any significant positive or negative deviation to the schedule or scope of a task shall be explained and documented by the Contractor in its annual, quarterly, and monthly progress, and Status and Management Report shall be reported to the Government within 2 weeks of identification as a Production or Delivery Problem Report (CDRL A011 / QASP #1).

3.5.3. Annual Program Reviews. The Contractor shall formally present the prior year's progress as part of an annual program review (for example, the IPR). The content of the briefing shall include but not be limited to the following: completed tasks within the year, highlights of completed tasks, summary of results from in-process studies, schedule updates, summary of results from completed studies, risks/issues, and funding execution. The annual program reviews shall be held at Fort Detrick, MD and may be held in conjunction with the integrated product team (IPT) meetings with senior leadership. Additional requests for travel to Fort Detrick, MD may be requested by the Government as needed (CDRL A011 / QASP #1).

3.5.4. FDA Communication and Study Reports. The Contractor shall provide the COR with FDA Communication and Study Reports. Regulatory documents including informal emails sent to the FDA are sent concurrently to the Government. Meeting notes shall be sent to the Government if efforts to attend verbal meetings (such as phone calls or meetings at the FDA) are not possible. Copies of informal and formal regulatory communications received from the FDA shall be sent within three (3) business days of receipt. Copies of Clinical Monitoring Reports should be sent within 30 business days of receipt (CDRL A013 / QASP #7).

3.5.5. Trip Reports. The Contractor shall provide Trip Reports within five (5) business days for trips that have been requested by the Government. The report should describe the purpose, results of the trip, and actual costs (CDRL A001 / QASP #1).

3.5.6. The Contractor shall assist in Kick-Off, coordination, progress update, and informational meetings.

3.5.7. The Contractor shall provide guidance and consult with Principal Investigator, senior staff, and clinical personnel during formal training and to review data from pilot trial. The Contractor shall provide recommendations for modifications to interventions when used with the PoNS^{TM} device, measurement tools and procedures.

3.5.8. The Contractor shall consult on data interpretation and collaborate on publications and presentations.

4. Deliverables:

The Contractor shall provide deliverables as described in the below chart.

Deliverable Table

Item	PWS Ref	Title	Distribution	E	Initial & Subsequent
1	2.2.1.1.	Program Manager Point of Contact	COR	1	Upon award of contract
2	3.1.1.	Final Project Management Plan (A001)	COR	1	Within 30 Calendar days after contract award; update quarterly
3	3.1.1.	Final Integrated Master Schedule (CDRL A001)	COR	1	Within 30 Calendar days after contract award; update quarterly
4	3.1.1.	Risk Management Plan (CDRL A001)	COR	1	Within 30 Calendar days after contract award; updated quarterly
5	3.1.2.	Quality Control Plan (CDRL A002)	COR	1	Within 30 Calendar days after contract award; update as needed; review quarterly
6	3.1.3.	IRB-approved Clinical Protocol for each Study Site (CDRL A003)	COR	1	Within 3 months of award of contract
7	3.1.3.	Statistical Analysis Plan (CDRL A003)	COR	1	Within 3 months of award of contract
8	3.1.3.	Clinical Monitoring Plan (CDRL A003)	COR	1	Within 3 months of award of contract
9	3.1.3.	Data Management Plan (CDRL A003)	COR	1	Within 3 months of award of contract
10	3.1.3.	Proposed Clinical Data Management System (CDRL A003)	COR	1	Within 3 months of award of contract
11	3.1.3.	Sample Case Report Forms (CDRL A003)	COR	1	Within 3 months of award of contract
12	3.1.3.	End User Guidelines (CDRL A003)	COR	1	Within 3 months of award of contract
13	3.1.3.	Recruitment and Retention Plan for each Clinical Site (CDRL A003)	COR	1	Within 3 months of award of contract

Item	PWS Ref	Title	Distribution	E	Initial & Subsequent
14	3.1.4.	IRB Approvals (CDRL A004)	COR	1	Within 3 months of award of contract and prior to start of clinical trial
15	3.1.5.	Representative Test Articles (sent to study sites) (CDRL A005)	COR	1	Prior to start of clinical trial
16	3.1.5.	Contingency Manufacturing Plan (CDRL A005)	COR	1	Prior to start of clinical trial
17	3.2.1.	Conduct Clinical Trial (CDRL A006)	COR	1	Copy of agreement with each study site prior to the start of the trial; monthly status report
18	3.2.2.	Interim Clinical Study Report & Mitigation Plan (CDRL A007)	COR		Within 30 days of completion of n = 60 subjects (and/or a proportionate amount consistent with FDA guidance)
19	3.3.1.	Final Clinical Study Report (CDRL A008)	COR	1	Within 75 days after completion of study
20	3.3.2.	FDA Submission Packet (CDRL A009)	COR	1	Concurrently with FDA submission
21	3.3.3.	Final Report	COR	1	Within 30 days after end of contract
22	3.3.4.	Technical Data Packet (CDRL A010)	COR	1	Seven (7) business days upon request and final TDP at end of contract
23	3.4.1.	FDA cleared PoNS^{TM} Devices	COR	N A	Within 10 business days of FDA clearance (2 devices)
24	3.5.1.	Monthly Progress, Status, and Management Reports (CDRL A011)	COR	1	Monthly reports due the 10th day of each month.
25	3.5.1.	Quarterly Progress, Status, and Management Reports (CDRL A011)	COR	1	Quarterly reports due the 15th day after end of each quarter.
26	3.5.1.	Annual Progress, Status, and Management Reports (CDRL A011)	COR		Annual reports due the 15th day after end of each year
27	3.5.2.	Production or Delivery Problem Reports (CDRL A012)	COR	1	Within 2 weeks of identification of deviation to schedule or scope of any task as needed
28	3.5.3.	Annual Program Reviews	IPT	N A	Annually In Process Review at Fort Detrick, MD
29	3.5.4.	FDA Communication and Study Reports (CDRL A013)	COR	1	Concurrently and/or 3 business days as applicable (see PWS 3.1.18.)

Item	PWS Ref	Title	Distribution	E	Initial & Subsequent
30	3.5.5.	Trip Reports	COR	1	Within 5 business days for Government requested travel

5. List of Acronyms:

AMEDD	Army Medical Department
CFR	Code of Federal Regulations
CONUS	Continental United States (excludes Alaska and Hawaii)
COR	Contracting Officer Representative
CRO	Clinical Research Organization
DD250	Department of Defense Form 250 (Receiving Report)
DD254	Department of Defense Contract Security Requirement List
DFARS	Defense Federal Acquisition Regulation Supplement
DoD	Department of Defense
FAR	Federal Acquisition Regulation
FDA	United States Food and Drug Administration
HIPAA	Health Insurance Portability and Accountability Act of 1996
IAW	In Accordance With
IMS	Integrated Master Schedule
IRB	Institutional Review Board
KO	Contracting Officer
n	Number of Research Subjects
NA	Not Applicable
NDA	Non-disclosure Agreement
NHC	NeuroHabilitation Corporation
OCI	Organizational Conflict of Interest
OCONUS	Outside Continental United States (includes Alaska and Hawaii)
ODC	Other Direct Costs
PM	Project Manager
PoNS™	Portable Neuromodulation Stimulator
PWS	Performance Work Statement
QA	Quality Assurance
QAP	Quality Assurance Program
QASP	Quality QAP Assurance Surveillance Plan
QC	Quality Control
QCP	Quality Control Plan
QSR	Quality Systems Regulations
TDP	Technical Data Packet
TBI	Traumatic Brain Injury
USAMMA	United States Army Medical Materiel Agency
USAMRMC	United States Medical Research and Materiel Command

CONTRACTOR MANPOWER REPORTING

Contractor Manpower Reporting (CMR) for the Base Period. Input for Contract Services information in the web site operated and maintained by the Assistant Secretary of the Army (Manpower & Reserve Affairs). See the "Contractor Manpower Reporting" clause for specific reporting information. Reporting period will be the period of performance not to exceed 12 months ending 30 September of each Government fiscal year and must be reported by 31 October of each calendar year. The Contract SHALL provide evidence of compliance with the CMR requirement to the Contracting Officer's Representative (COR), Contract Specialist, and Contracting Officer no later than 15 November of each calendar year.

The contractor does not propose any additional costs related to Contractor Manpower Reporting.

CLAUSES INCORPORATED BY FULL TEXT

CONTRACTOR MANPOWER REPORTING (CMR) - (ACCOUNTING FOR CONTRACT SERVICES) (APR 2011) (USAMRAA)

The Office of the Assistant Secretary of the Army (Manpower & Reserve Affairs) operates and maintains a secure Army data collection site where the contractor will report ALL contractor manpower (including sub-contractor manpower) required for performance of this contract. The contractor is required to completely fill in all the information in the format using the following web address: https://cmra.army.mil. The required information includes: (l) Contract Number; (2) Delivery Order Number (If applicable); (3) Task Order Number (If applicable); (4) Requiring Activity Unit Identification Code (UIC); (5) Command; (6) Contractor Contact Information; (7) Federal Service Code (FSC); (8) Direct Labor Hours; (9) Direct Labor Dollars; and, (10) Location. In the event the Contracting Officer's Representative (COR)/Contracting Officer's Technical Representative (COTR) has not entered their data requirements first, the contractor must also enter the COR/COTR required data with the exception of fund cite, obligations, and disbursement data. The CMRA help desk can be reach at 703-695-5103 or 703-695-5058 for any technical questions. The help desk can also be contacted via email: contractormanpower@hqda.army.mil. As part of its quote or offer, the contractor will also provide the estimated total cost (if any) incurred to comply with this reporting requirement. The reporting period will be the period of performance not to exceed 12 months ending 30 September of each government fiscal year and must be reported by 31 October of each calendar year.

Section E - Inspection and Acceptance

INSPECTION AND ACCEPTANCE TERMS

Supplies/services will be inspected/accepted at:

CLIN	INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
0001	Destination	Government	Destination	Government
0002	Destination	Government	Destination	Government
0003	Destination	Government	Destination	Government

CLAUSES INCORPORATED BY REFERENCE

52.246-5	Inspection Of Services Cost-Reimbursement	APR 1984
52.246-8	Inspection Of Research And Development Cost Reimbursement	MAY 2001

Section F - Deliveries or Performance

DELIVERY INFORMATION

CLIN	DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC
0001	POP 01-JUL-2015 TO 31-DEC-2016	N/A	US ARMY MEDICAL MATERIEL AGENCY US ARMY MEDICAL MATERIEL AGENCY 693 NEIMAN STREET FREDERICK MD 21702 301-619-4518 FOB: Destination	W25MWY
0002	POP 01-JUL-2015 TO 30-DEC-2016	N/A	(SAME AS PREVIOUS LOCATION) FOB: Destination	W25MWY
0003	POP 01-JUL-2015 TO 30-DEC-2016	N/A	(SAME AS PREVIOUS LOCATION) FOB: Destination	W25MWY

CLAUSES INCORPORATED BY REFERENCE

52.242-15	Stop-Work Order	AUG 1989

Section G - Contract Administration Data

ACCOUNTING AND APPROPRIATION DATA

AA: 097201420150130000 18N10337374255	R.0011882.4.11	6100.9000021001
COST CODE: A7466		
AMOUNT: $2,996,244.00		
CIN GFEBS001055363000001: $217,975.21		
CIN GFEBS001055363000002: $2,763,289.24		
CIN GFEBS001055363000003: $14,979.55		

CLAUSES INCORPORATED BY REFERENCE

252.201-7000	Contracting Officer's Representative	DEC 1991

CLAUSES INCORPORATED BY FULL TEXT

52.004-4002 Contractor Performance Assessment Reporting System (CPARS) (USAMRAA) (September 2009)

The Contractor Performance Assessment Reporting System (CPARS) has been adopted electronically to capture assessment data and manage the evaluation process. CPARS is used to assess a contractor's performance and provide a record, both positive and negative, on a given contract during a specific period of time. The CPARS Automated Information System (AIS) collection tool and other CPARS information can be accessed at https://www.cpars.csd.disa.mil. CPARS collects contractor performance information and passes it to the Federal Past Performance Information Retrieval System (PPIRS) where it can be retrieved by Federal Government Agencies including the DoD Services. The CPARS process is designed with a series of checks and balances to facilitate the objective and consistent evaluation of contractor performance. Both government and contractor program management perspectives are captured on the CPAR form and together make a complete CPAR. The Contractor shall assign and provide to the Contracting Officer's Representative (COR), within 10 calendar days after award, the name, title, email address and phone number of the designated Contractor Representative (CR) within their firm who will be responsible for CPAR information and reviewing the Government's proposed assessment for the period of performance. A User ID and Password for the CPARS will be provided to the designated CR for this purpose of accessing the CPARS. The CR has the authority to: Receive the Government evaluation; Review/comment/return the evaluation to the Government within 30 calendar days after the Government's evaluation is completed; Request a meeting to discuss the CPAR. This meeting must be requested, in writing, no later than seven calendar days from the receipt of the CPAR and must be held during the contractor’s 30-day review period. The CR must either concur or nonconcur to each CPAR.

CLAUSES INCORPORATED BY FULL TEXT

252.232 -7006 WIDE AREA WORKFLOW PAYMENT INSTRUCTIONS (MAY 2013)

(a) Definitions. As used in this clause--

Department of Defense Activity Address Code (DoDAAC) is a six position code that uniquely identifies a unit, activity, or organization.

Document type means the type of payment request or receiving report available for creation in Wide Area WorkFlow (WAWF).

Local processing office (LPO) is the office responsible for payment certification when payment certification is done external to the entitlement system.

(b) Electronic invoicing. The WAWF system is the method to electronically process vendor payment requests and receiving reports, as authorized by DFARS 252.232 -7003, Electronic Submission of Payment Requests and Receiving Reports.

(c) WAWF access. To access WAWF, the Contractor shall--

(1) Have a designated electronic business point of contact in the System for Award Management at https://www.acquisition.gov; and

(2) Be registered to use WAWF at https://wawf.eb.mil/ following the step-by-step procedures for self-registration available at this Web site.

(d) WAWF training. The Contractor should follow the training instructions of the WAWF Web-Based Training Course and use the Practice Training Site before submitting payment requests through WAWF. Both can be accessed by selecting the “Web Based Training” link on the WAWF home page at https://wawf.eb.mil/.

(e) WAWF methods of document submission. Document submissions may be via Web entry, Electronic Data Interchange, or File Transfer Protocol.

(f) WAWF payment instructions. The Contractor must use the following information when submitting payment requests and receiving reports in WAWF for this contract/order:

(1) Document type. The Contractor shall use the following document type(s).

Invoice 2-in-1 Services (Services Only)

(Contracting Officer: Insert applicable document type(s). Note: If a “Combo” document type is identified but not supportable by the Contractor's business systems, an “Invoice” (stand-alone) and “Receiving Report” (stand-alone) document type may be used instead.)

(2) Inspection/acceptance location. The Contractor shall select the following inspection/acceptance location(s) in WAWF, as specified by the contracting officer.

Not Applicable

(Contracting Officer: Insert inspection and acceptance locations or “Not applicable”.)

(3) Document routing. The Contractor shall use the information in the Routing Data Table below only to fill in applicable fields in WAWF when creating payment requests and receiving reports in the system.

Routing Data Table*

Field Name in WAWF	Data to be entered in WAWF
Pay Official DoDAAC	HQ0490
Issue By DoDAAC	W81XWH
Admin DoDAAC	W81XWH
Inspect By DoDAAC	W25MWY
Ship To Code	W25MWY
Ship From Code	_____
Mark For Code	_____
Service Approver (DoDAAC)	HAA391
Service Acceptor (DoDAAC)	W25MWY
Accept at Other DoDAAC	N/A
LPO DoDAAC	N/A
DCAA Auditor DoDAAC	HAA391
Other DoDAAC(s)	N/A

(*Contracting Officer: Insert applicable DoDAAC information or “See schedule” if multiple ship to/acceptance locations apply, or “Not applicable.”)

(4) Payment request and supporting documentation. The Contractor shall ensure a payment request includes appropriate contract line item and subline item descriptions of the work performed or supplies delivered, unit price/cost per unit, fee (if applicable), and all relevant back-up documentation, as defined in DFARS Appendix F, (e.g. timesheets) in support of each payment request.

(5) WAWF email notifications. The Contractor shall enter the email address identified below in the “Send Additional Email Notifications” field of WAWF once a document is submitted in the system.

Scott.d.colmyer.civ@mail.mil

(Contracting Officer: Insert applicable email addresses or “Not applicable.”)

(g) WAWF point of contact. (1) The Contractor may obtain clarification regarding invoicing in WAWF from the following contracting activity's WAWF point of contact.

Not Applicable

(Contracting Officer: Insert applicable information or “Not applicable.”)

(2) For technical WAWF help, contact the WAWF helpdesk at 866-618-5988.

(End of clause)

Section H - Special Contract Requirements

CLAUSES INCORPORATED BY FULL TEXT

ORGANIZATIONAL AND CONSULTANT CONFLICTS OF INTEREST (MAR 1999) (USAMRAA)

a. It is recognized by the parties hereto that the effort performed by the contractor under this contract is of a nature that it creates a potential organizational conflict of interest as is contemplated under the FAR Subpart 9.5.

b. In the performance of this contract, the contractor may have access to data which is procurement sensitive or is proprietary to other companies, Government consultants or advisors, or the Government. The contractor agrees that he will not utilize such procurement sensitive or proprietary data in performance of future competitive contracts, for studies in the same field, procured either through sealed bids or competitive negotiations. The contractor further agrees not to act as a subcontractor or consultant to any other prime contractor or subcontractor seeking to utilize such data.

c. The contractor will include the provisions of paragraphs a and b in every first tier subcontract for performance of any portion of this requirement.

d. This clause shall have effect from 01 July 2015 to 31 December 2016.

CLAUSES INCORPORATED BY FULL TEXT

GOOD LABORATORY PRACTICES (DEC 2006) (USAMRAA)

The conduct of studies on investigational new drugs or devices shall comply with the GOOD LABORATORY PRACTICE (GLP) FOR NONCLINICAL LABORATORY STUDIES regulations 21 CFR 58. The contractor shall notify the Administrative Contracting Officer by telephone immediately upon announcement by a representative of the Food and Drug Administration (FDA) of an inspection of studies performed under this contract. In addition to the FDA representative, the Contracting Officer's Representative (COR) shall have access to the contractor's records and specimens. With reference to paragraph 58.195(h) of the GLP regulations, the contractor shall notify the COR in writing in addition to the FDA, should the contractor go out of business and/or transfer the records during the periods prescribed in paragraph 58.195. On expiration or termination of the contract, the contractor shall notify the COR of any remaining unused test articles.

CLAUSES INCORPORATED BY FULL TEXT

INVESTIGATING AND REPORTING POSSIBLE SCIENTIFIC MISCONDUCT (MAR 1999) (USAMRAA)

a. "Misconduct" or "Misconduct in Science" is defined as fabrication, falsification, plagiarism, or other practices that seriously deviate from those that are commonly accepted within the scientific community for proposing, conducting or reporting research. It does not include honest error or honest differences in interpretations or judgments of data.

b. Contractors shall foster a research environment that prevents misconduct in all research and that deals forthrightly with possible misconduct associated with research for which U.S. Army Medical Research and Materiel Command funds have been provided or requested.

c. The contractor agrees to:
(1) Establish and keep current an administrative process to review, investigate, and report allegations of misconduct in science in connection with research conducted by the contractor;
(2) Comply with its own administrative process;
(3) Inform its scientific and administrative staff of the policies and procedures and the importance of compliance with those policies and procedures;
(4) Take immediate and appropriate action as soon as misconduct on the part of employees or persons within the organization's control is suspected or alleged; and
(5) Report to the Administrative Contracting Officer (ACO) a decision to initiate an investigation into possible scientific misconduct.

d. The contractor is responsible for notifying the ACO of appropriate action taken if at any stage of an inquiry or investigation any of the following conditions exist:
(1) An immediate health hazard is involved;
(2) There is an immediate need to protect Federal funds or equipment;
(3) A probability exists that the alleged incident will be reported publicly; or
(4) There is a reasonable indication of possible criminal violation.

PROHIBITION OF HUMAN RESEARCH (JUN 2013) (USAMRAA)

**** PROHIBITION – READ FURTHER FOR DETAILS ****

Research under this award involving the use of human subjects, to include the use of human anatomical substances or identifiable private information (human data), shall not begin until the USAMRMC's Office of Research Protections (ORP) provides authorization that the research may proceed. Written approval to begin research will be issued from the USAMRMC ORP, under separate notification to the contractor. Written approval from the USAMRMC ORP is also required for any subcontractor that will use funds from this award to conduct research involving human subjects.

Research involving human subjects shall be conducted in accordance with the protocol submitted to and approved by the USAMRMC ORP. Complete study records shall be maintained for each human research study and shall be made available for review by representatives of the USAMRMC. Research records shall be stored in a confidential manner so as to protect the confidentiality of subject information.

The contractor is required to adhere to the following reporting requirements:

Submission of major modifications to the protocol, continuing review documentation, and the final report are required as outlined in the USAMRMC ORP approval memorandum.

Unanticipated problems involving risks to subjects or others, subject deaths related to participation in the research, clinical holds (voluntary or involuntary), and suspension or termination of this research by the IRB, the institution, the Sponsor, or regulatory agencies, shall be promptly reported to the USAMRMC ORP and the USAMRAA Contracting Office.

The knowledge of any pending compliance inspection/visits by the FDA, ORP, or other government agency concerning this clinical investigation or research, the issuance of Inspection Reports, FDA Form 483, warning letters or actions taken by any Regulatory Agencies including legal or medical actions, and any instances of serious or continuing noncompliance with regulatory requirements that relate to this clinical investigation or research, shall be reported immediately to the USAMRMC ORP and the USAMRAA Contracting Office.

Non-compliance with these terms and conditions may result in withholding of funds and/or the termination of the award.

52.035 -4035 PROHIBITION OF USE OF LABORATORY ANIMALS (JUN 2013) (USAMRAA)

** PROHIBITION – READ FURTHER FOR DETAILS **

Notwithstanding any other terms and conditions contained in this award or incorporated by reference herein, the contractor is expressly forbidden to use or subcontract for the use of laboratory animals in any manner whatsoever without the express written approval of the USAMRMC, Animal Care and Use Review Office (ACURO). Written authorization to begin research under the applicable protocol(s) proposed for this award will be issued in the form of an approval letter from the USAMRMC ACURO to the contractor with a copy to the USAMRAA Contracting Office. Furthermore, modifications to already approved protocols require approval by ACURO prior to implementation. Once approved, notification must be given immediately to USAMRAA contracting. For each fiscal year, the contractor shall maintain, and upon request from ACURO, submit animal usage information. Non-compliance with any of these terms and conditions may result in withholding of funds and/or ther terminations of the award.

52.035 -4036 PROHIBITION OF USE OF HUMAN CADAVERS (JUN 2013) (USAMRAA)

**** PROHIBITION – READ FURTHER FOR DETAILS****

Research, development, testing and evaluation (RDT&E), education or training activities involving human cadavers under this award shall not begin until approval is granted in accordance with the Army Policy for Use of Human Cadavers for RDT&E, Education, or Training, 20 April 2012 (https://mrmc.amedd.army.mil/index.cfm?pageid=research_ protections.overview). The USAMRMC Office of Research Protections (ORP) is the Action Office (hrpo@amedd.army.mil) for this policy. Approval must be obtained from the Head of the Army organization that is supporting/funding the activity involving cadavers as described in the Army Policy for Use of Human Cadavers. For certain activities involving cadavers, approval must also be obtained from ORP. Award contractors must coordinate with the supporting/funding Army organization to ensure that proper approvals are obtained. Written approvals to begin the activity will be issued under separate notification to the contractor. Non-compliance with these terms and conditions may result in withholding of funds and/or the termination of the award.

CONTRACTOR IDENTIFICATION (DEC 2005) (USAMRAA)

When contractor personnel perform the services required in this contract on a Government installation they are required to possess and wear an identification badge that displays his or her name and the name of the Company. The contractor shall ensure that contractor personnel identify themselves as contractors when attending meetings, answering Government telephones, providing any type of written correspondence, or working in situations where their actions could be construed as official Government acts.

While performing in a contractor capacity, contractor personnel shall refrain from using their retired or reserve component military rank or title in all written or verbal communications.

REPORTS, MANUSCRIPTS AND PUBLIC RELEASES (DEC 2006) (USAMRAA)

a. Contractors are encouraged to publish results of research supported by the US Army Medical Research and Materiel Command (USAMRMC) in appropriate media forum. Any publication, report or public release, which may create a statutory bar to the issuance of a patent on any subject invention, shall be coordinated with appropriate patent counsel.

b. Manuscripts intended for publication in any media shall be submitted to the Contracting Officer and Contracting Officer's Representative (COR), simultaneously with submission for publication. Review of such manuscripts is for comment to the Principal Investigator, not for approval or disapproval. Courtesy copies of the reprint shall be forwarded to the Contracting Officer and COR, even though publication may be subsequent to the expiration of the contract.

c. The Contractor shall notify the Contracting Officer of planned news releases, planned publicity, advertising material concerning contract work, and planned presentations to scientific meetings, prior to public release. This is not intended to restrict dissemination of research information but to allow USAMRMC advance notice in order to adequately respond to inquiries.

d. Manuscripts, reports, public releases and abstracts, which appear in professional journals, media and programs, shall include the following statements:

(l) "This work is supported by the US Army Medical Research and Materiel Command under Contract No. W81XWH-15-C-0096"

(2) "The views, opinions and/or findings contained in this report are those of the author(s) and should not be construed as an official Department of the Army position, policy or decision unless so designated by other documentation."

(3) As applicable, if the research involves the use of animals, the Contractor must include the following statement: "In conducting research using animals, the investigator(s) adhered to the Animal Welfare Act Regulations and other Federal statutes relating to animals and experiments involving animals and the principles set forth in the current version of the Guide for Care and Use of Laboratory Animals, National Research Council."

(4) As applicable, if the research involves human use, the Contractor must include the following statement: "In the conduct of research where humans are the subjects, the investigator(s) adhered to the policies regarding the protection of human subjects as prescribed by Code of Federal Regulations (CFR) Title 45, Volume 1, Part 46; Title 32, Chapter 1, Part 219; and Title 21, Chapter 1, Part 50 (Protection of Human Subjects)."

(5) As applicable, if the research involves the use of recombinant DNA, the Contractor must include the following statement: "In conducting work involving the use of recombinant DNA the investigator(s) adhered to the current version of the National Institutes of Health (NIH) Guidelines for Research Involving Recombinant DNA Molecules."

TRAVEL (JULY 2007) (USAMRAA)

a. Approval of Foreign Travel. The cost of foreign travel is allowable only when the specific written approval of the Contracting Officer is obtained prior to commencing the trip. Approval shall be requested at least 90 calendar days before the scheduled departure date in order that all necessary clearances may be processed. Each individual trip must be approved separately, even though it may have been included in a previously approved budget. Foreign travel under this contract is defined as any travel outside of the United States and its territories and possessions.

b. Costs incurred by contractor personnel on official company business, whether foreign travel and/or domestic/local travel, are allowable, subject to the limitations contained in the Federal Acquisition Regulation (FAR) clause at 52.216 -7, Allowable Cost and Payment, incorporated into this contract.

Section I - Contract Clauses

REGULATORY RIGHTS
REGULATORY RIGHTS IN EVENT OF PRODUCT DEVELOPMENT FAILURES

This contract includes research with an investigational drug, biologic or medical device that is regulated by the U.S. Food and Drug Administration (FDA) and requires FDA pre-market approval or clearance before commercial marketing may begin. It is expected that this contract will result in the FDA clearance and commercialization of the Portable Neuromodulation Stimulator (PoNS) device. The Contractor is the sponsor of the Regulatory Application (an investigational new drug application (IND), investigational device exemption (IDE), new drug application (NDA), biologics license application (BLA), premarket approval application (PMA), or 510(k) pre-market notification filing (510(k)) or another regulatory filing submitted to FDA) that controls the research under this contract. As the sponsor of the Regulatory Application to FDA (as the terms “sponsor” and “applicant” are defined or used in at 21 CFR §§3.2(c), 312.5, 600.3(t), 812.2(b), 812 Subpart C, or 814.20), the Contractor has certain standing before the FDA that entitles it to exclusive communications related to the Regulatory Application. This provision protects the return on research and development investment made by the U.S. Army Medical Research and Materiel Command (USAMRMC) in the event of certain regulatory product development failures related to the Technology.

The Contractor agrees to the following:

a. Contractor will, within three (3) business days of receipt, provide USAMRMC with all communications and summaries thereof, both formal and informal, to or from FDA regarding the Technology and ensure that USAMRMC representatives are given advance notice of and are invited to participate with at least two (2) representatives in any formal or informal sponsor meetings with FDA;

b. If contract is to be terminated or is about to expire prior to the time the Contractor obtains FDA approval or clearance ; or the Contractor fails to commercially market the regulated technology within three (3) years after the FDA issues approval or clearance, the Contractor, upon the request of the Government:

(i) shall transfer possession, ownership and sponsorship or holdership of any Regulatory Application (including any associated expedited review designation, priority review voucher, or marketing exclusivity eligibility or award), regulatory correspondence, and supporting regulatory information related to the Technology to USAMRMC or its designee;

(ii) shall inform FDA of the transfer of sponsorship or holdership of the Regulatory Application transferred under section (c)(i) above.

c. The terms of this provision and its derivative obligations:

(i) will be included in any license, sale or transfer by the Contractor to a third party of any intellectual property covered by section (b) above.

(ii) will survive the acquisition or merger of the Contractor by or with any third party.

(iii) will be included in any subcontracts relating to the development of the Technology.

(iv) will survive the expiration of this contract.

CLAUSES INCORPORATED BY REFERENCE

52.202-1	Definitions	NOV 2013

52.203-3	Gratuities	APR 1984
52.203-5	Covenant Against Contingent Fees	MAY 2014
52.203-6	Restrictions On Subcontractor Sales To The Government	SEP 2006
52.203-7	Anti-Kickback Procedures	MAY 2014
52.203-12	Limitation On Payments To Influence Certain Federal Transactions	OCT 2010
52.203-17	Contractor Employee Whistleblower Rights and Requirement To Inform Employees of Whistleblower Rights	APR 2014
52.204-4	Printed or Copied Double-Sided on Postconsumer Fiber Content Paper	MAY 2011
52.204-9	Personal Identity Verification of Contractor Personnel	JAN 2011
52.204-10	Reporting Executive Compensation and First-Tier Subcontract Awards	JUL 2013
52.204-13	System for Award Management Maintenance	JUL 2013
52.209-6	Protecting the Government's Interest When Subcontracting With Contractors Debarred, Suspended, or Proposed for Debarment	AUG 2013
52.209-9	Updates of Publicly Available Information Regarding Responsibility Matters	JUL 2013
52.209-10	Prohibition on Contracting With Inverted Domestic Corporations	DEC 2014
52.215-8	Order of Precedence--Uniform Contract Format	OCT 1997
52.215-23	Limitations on Pass-Through Charges	OCT 2009
52.217-2	Cancellation Under Multiyear Contracts	OCT 1997
52.219-8	Utilization of Small Business Concerns	OCT 2014
52.222-1	Notice To The Government Of Labor Disputes	FEB 1997
52.222-3	Convict Labor	JUN 2003
52.222-50	Combating Trafficking in Persons	MAR 2015
52.223-6	Drug-Free Workplace	MAY 2001
52.223-17	Affirmative Procurement of EPA-Designated Items in Service and Construction Contracts	MAY 2008
52.223-18	Encouraging Contractor Policies To Ban Text Messaging While Driving	AUG 2011
52.224-1	Privacy Act Notification	APR 1984
52.224-2	Privacy Act	APR 1984
52.225-13	Restrictions on Certain Foreign Purchases	JUN 2008
52.227-1	Authorization and Consent	DEC 2007
52.227-1 Alt I	Authorization And Consent (Dec 2007) - Alternate I	APR 1984
52.227-2	Notice And Assistance Regarding Patent And Copyright Infringement	DEC 2007
52.228-7	Insurance--Liability To Third Persons	MAR 1996
52.232-23	Assignment Of Claims	MAY 2014
52.232-33	Payment by Electronic Funds Transfer--System for Award Management	JUL 2013
52.232-39	Unenforceability of Unauthorized Obligations	JUN 2013
52.232-40	Providing Accelerated Payments to Small Business Subcontractors	DEC 2013
52.233-1	Disputes	MAY 2014
52.233-3 Alt I	Protest After Award (Aug 1996) - Alternate I	JUN 1985
52.233-4	Applicable Law for Breach of Contract Claim	OCT 2004
52.239-1	Privacy or Security Safeguards	AUG 1996
52.242-1	Notice of Intent to Disallow Costs	APR 1984
52.242-2	Production Progress Reports	APR 1991
52.242-3	Penalties for Unallowable Costs	MAY 2014
52.242-4	Certification of Final Indirect Costs	JAN 1997

52.242-13	Bankruptcy	JUL 1995
52.242-13	Bankruptcy	JUL 1995
52.243-6	Change Order Accounting	APR 1984
52.244-5	Competition In Subcontracting	DEC 1996
52.244-6	Subcontracts for Commercial Items	OCT 2014
52.246-25	Limitation Of Liability--Services	FEB 1997
52.249-6	Termination (Cost Reimbursement)	MAY 2004
52.249-14	Excusable Delays	APR 1984
52.253-1	Computer Generated Forms	JAN 1991
252.203-7000	Requirements Relating to Compensation of Former DoD Officials	SEP 2011
252.203-7001	Prohibition On Persons Convicted of Fraud or Other Defense- Contract-Related Felonies	DEC 2008
252.204-7000	Disclosure Of Information	AUG 2013
252.204-7003	Control Of Government Personnel Work Product	APR 1992
252.204-7012	Safeguarding of Unclassified Controlled Technical Information	NOV 2013
252.209-7004	Subcontracting With Firms That Are Owned or Controlled By The Government of a Terrorist Country	DEC 2014
252.223-7004	Drug Free Work Force	SEP 1988
252.225-7993 (Dev)	Prohibition on Contracting with the Enemy (Deviation)	SEP 2014
252.227-7001	Release Of Past Infringement	AUG 1984
252.227-7010	License to Other Government Agencies	AUG 1984
252.227-7013	Rights in Technical Data--Noncommercial Items	FEB 2014
252.227-7014	Rights in Noncommercial Computer Software and Noncommercial Computer Software Documentation	FEB 2014
252.227-7016	Rights in Bid or Proposal Information	JAN 2011
252.227-7030	Technical Data--Withholding Of Payment	MAR 2000
252.227-7037	Validation of Restrictive Markings on Technical Data	JUN 2013
252.227-7039	Patents--Reporting Of Subject Inventions	APR 1990
252.232-7003	Electronic Submission of Payment Requests and Receiving Reports	JUN 2012
252.246-7001	Warranty Of Data	MAR 2014

CLAUSES INCORPORATED BY FULL TEXT

52.216 -7 ALLOWABLE COST AND PAYMENT (JUN 2013)

(a) Invoicing.

(1) The Government will make payments to the Contractor when requested as work progresses, but (except for small business concerns) not more often than once every 2 weeks, in amounts determined to be allowable by the Contracting Officer in accordance with Federal Acquisition Regulation (FAR) subpart 31.2 in effect on the date of this contract and the terms of this contract. The Contractor may submit to an authorized representative of the Contracting Officer, in such form and reasonable detail as the representative may require, an invoice or voucher supported by a statement of the claimed allowable cost for performing this contract.

(2) Contract financing payments are not subject to the interest penalty provisions of the Prompt Payment Act. Interim payments made prior to the final payment under the contract are contract financing payments, except interim payments if this contract contains Alternate I to the clause at 52.232 -25.

(3) The designated payment office will make interim payments for contract financing on the 30th day after the designated billing office receives a proper payment request.

In the event that the Government requires an audit or other review of a specific payment request to ensure compliance with the terms and conditions of the contract, the designated payment office is not compelled to make payment by the specified due date.

(b) Reimbursing costs. (1) For the purpose of reimbursing allowable costs (except as provided in subparagraph (b)(2) of the clause, with respect to pension, deferred profit sharing, and employee stock ownership plan contributions), the term "costs" includes only--

(i) Those recorded costs that, at the time of the request for reimbursement, the Contractor has paid by cash, check, or other form of actual payment for items or services purchased directly for the contract;

(ii) When the Contractor is not delinquent in paying costs of contract performance in the ordinary course of business, costs incurred, but not necessarily paid, for--

(A) Supplies and services purchased directly for the contract and associated financing payments to subcontractors, provided payments determined due will be made--

(1) In accordance with the terms and conditions of a subcontract or invoice; and

(2) Ordinarily within 30 days of the submission of the Contractor's payment request to the Government;

(B) Materials issued from the Contractor's inventory and placed in the production process for use on the contract;

(C) Direct labor;

(D) Direct travel;

(E) Other direct in-house costs; and

(F) Properly allocable and allowable indirect costs, as shown in the records maintained by the Contractor for purposes of obtaining reimbursement under Government contracts; and

(iii) The amount of financing payments that have been paid by cash, check, or other forms of payment to subcontractors.

(2) Accrued costs of Contractor contributions under employee pension plans shall be excluded until actually paid unless--

(i) The Contractor's practice is to make contributions to the retirement fund quarterly or more frequently; and

(ii) The contribution does not remain unpaid 30 days after the end of the applicable quarter or shorter payment period (any contribution remaining unpaid shall be excluded from the Contractor's indirect costs for payment purposes).

(3) Notwithstanding the audit and adjustment of invoices or vouchers under paragraph (g) of this clause, allowable indirect costs under this contract shall be obtained by applying indirect cost rates established in accordance with paragraph (d) of this clause.

(4) Any statements in specifications or other documents incorporated in this contract by reference designating performance of services or furnishing of materials at the Contractor's expense or at no cost to the Government shall be disregarded for purposes of cost-reimbursement under this clause.

(c) Small business concerns. A small business concern may receive more frequent payments than every 2 weeks.

(d) Final indirect cost rates. (1) Final annual indirect cost rates and the appropriate bases shall be established in accordance with Subpart 42.7 of the Federal Acquisition Regulation (FAR) in effect for the period covered by the indirect cost rate proposal.

(2)(i) The Contractor shall submit an adequate final indirect cost rate proposal to the Contracting Officer (or cognizant Federal agency official) and auditor within the 6-month period following the expiration of each of its fiscal years. Reasonable extensions, for exceptional circumstances only, may be requested in writing by the Contractor and granted in writing by the Contracting Officer. The Contractor shall support its proposal with adequate supporting data.

(ii) The proposed rates shall be based on the Contractor's actual cost experience for that period. The appropriate Government representative and the Contractor shall establish the final indirect cost rates as promptly as practical after receipt of the Contractor's proposal.

(iii) An adequate indirect cost rate proposal shall include the following data unless otherwise specified by the cognizant Federal agency official:

(A) Summary of all claimed indirect expense rates, including pool, base, and calculated indirect rate.

(B) General and Administrative expenses (final indirect cost pool). Schedule of claimed expenses by element of cost as identified in accounting records (Chart of Accounts).

(C) Overhead expenses (final indirect cost pool). Schedule of claimed expenses by element of cost as identified in accounting records (Chart of Accounts) for each final indirect cost pool.

(D) Occupancy expenses (intermediate indirect cost pool). Schedule of claimed expenses by element of cost as identified in accounting records (Chart of Accounts) and expense reallocation to final indirect cost pools.

(E) Claimed allocation bases, by element of cost, used to distribute indirect costs.

(F) Facilities capital cost of money factors computation.

(G) Reconciliation of books of account (i.e., General Ledger) and claimed direct costs by major cost element.

(H) Schedule of direct costs by contract and subcontract and indirect expense applied at claimed rates, as well as a subsidiary schedule of Government participation percentages in each of the allocation base amounts.

(I) Schedule of cumulative direct and indirect costs claimed and billed by contract and subcontract.

(J) Subcontract information. Listing of subcontracts awarded to companies for which the contractor is the prime or upper-tier contractor (include prime and subcontract numbers; subcontract value and award type; amount claimed during the fiscal year; and the subcontractor name, address, and point of contact information).

(K) Summary of each time-and-materials and labor-hour contract information, including labor categories, labor rates, hours, and amounts; direct materials; other direct costs; and, indirect expense applied at claimed rates.

(L) Reconciliation of total payroll per IRS form 941 to total labor costs distribution.

(M) Listing of decisions/agreements/approvals and description of accounting/organizational changes.

(N) Certificate of final indirect costs (see 52.242 -4, Certification of Final Indirect Costs).

(O) Contract closing information for contracts physically completed in this fiscal year (include contract number, period of performance, contract ceiling amounts, contract fee computations, level of effort, and indicate if the contract is ready to close).

(iv) The following supplemental information is not required to determine if a proposal is adequate, but may be required during the audit process:

(A) Comparative analysis of indirect expense pools detailed by account to prior fiscal year and budgetary data.

(B) General organizational information and limitation on allowability of compensation for certain contractor personnel. See 31.205 -6(p). Additional salary reference information is available at http://www.whitehouse.gov/omb/procurement_index_exec_comp/.

(C) Identification of prime contracts under which the contractor performs as a subcontractor.

(D) Description of accounting system (excludes contractors required to submit a CAS Disclosure Statement or contractors where the description of the accounting system has not changed from the previous year's submission).

(E) Procedures for identifying and excluding unallowable costs from the costs claimed and billed (excludes contractors where the procedures have not changed from the previous year's submission).

(F) Certified financial statements and other financial data (e.g., trial balance, compilation, review, etc.).

(G) Management letter from outside CPAs concerning any internal control weaknesses.

(H) Actions that have been and/or will be implemented to correct the weaknesses described in the management letter from subparagraph G) of this section.

(I) List of all internal audit reports issued since the last disclosure of internal audit reports to the Government.

(J) Annual internal audit plan of scheduled audits to be performed in the fiscal year when the final indirect cost rate submission is made.

(K) Federal and State income tax returns.

(L) Securities and Exchange Commission 10-K annual report.

(M) Minutes from board of directors meetings.

(N) Listing of delay claims and termination claims submitted which contain costs relating to the subject fiscal year.

(O) Contract briefings, which generally include a synopsis of all pertinent contract provisions, such as: Contract type, contract amount, product or service(s) to be provided, contract performance period, rate ceilings, advance approval requirements, pre-contract cost allowability limitations, and billing limitations.

(v) The Contractor shall update the billings on all contracts to reflect the final settled rates and update the schedule of cumulative direct and indirect costs claimed and billed, as required in paragraph (d)(2)(iii)(I) of this section, within 60 days after settlement of final indirect cost rates.

(3) The Contractor and the appropriate Government representative shall execute a written understanding setting forth the final indirect cost rates. The understanding shall specify (i) the agreed-upon final annual indirect cost rates, (ii) the bases to which the rates apply, (iii) the periods for which the rates apply, (iv) any specific indirect cost items treated as direct costs in the settlement, and (v) the affected contract and/or subcontract, identifying any with advance agreements or special terms and the applicable rates. The understanding shall not change any monetary ceiling, contract obligation, or specific cost allowance or disallowance provided for in this contract. The understanding is incorporated into this contract upon execution.

(4) Failure by the parties to agree on a final annual indirect cost rate shall be a dispute within the meaning of the Disputes clause.

(5) Within 120 days (or longer period if approved in writing by the Contracting Officer) after settlement of the final annual indirect cost rates for all years of a physically complete contract, the Contractor shall submit a completion invoice or voucher to reflect the settled amounts and rates. The completion invoice or voucher shall include settled subcontract amounts and rates. The prime contractor is responsible for settling subcontractor amounts and rates included in the completion invoice or voucher and providing status of subcontractor audits to the contracting officer upon request.

(6)(i) If the Contractor fails to submit a completion invoice or voucher within the time specified in paragraph (d)(5) of this clause, the Contracting Officer may--

(A) Determine the amounts due to the Contractor under the contract; and

(B) Record this determination in a unilateral modification to the contract.

(ii) This determination constitutes the final decision of the Contracting Officer in accordance with the Disputes clause.

(e) Billing rates. Until final annual indirect cost rates are established for any period, the Government shall reimburse the Contractor at billing rates established by the Contracting Officer or by an authorized representative (the cognizant auditor), subject to adjustment when the final rates are established. These billing rates--

(1) Shall be the anticipated final rates; and

(2) May be prospectively or retroactively revised by mutual agreement, at either party's request, to prevent substantial overpayment or underpayment.

(f) Quick-closeout procedures. Quick-closeout procedures are applicable when the conditions in FAR 42.708(a) are satisfied.

(g) Audit. At any time or times before final payment, the Contracting Officer may have the Contractor's invoices or vouchers and statements of cost audited. Any payment may be (1) Reduced by amounts found by the Contracting Officer not to constitute allowable costs or (2) Adjusted for prior overpayments or underpayments.

(h) Final payment. (1) Upon approval of a completion invoice or voucher submitted by the Contractor in accordance with paragraph (d)(5) of this clause, and upon the Contractor's compliance with all terms of this contract, the Government shall promptly pay any balance of allowable costs and that part of the fee (if any) not previously paid.

(2) The Contractor shall pay to the Government any refunds, rebates, credits, or other amounts (including interest, if any) accruing to or received by the Contractor or any assignee under this contract, to the extent that those amounts are properly allocable to costs for which the Contractor has been reimbursed by the Government. Reasonable expenses incurred by the Contractor for securing refunds, rebates, credits, or other amounts shall be allowable costs if approved by the Contracting Officer. Before final payment under this contract, the Contractor and each assignee whose assignment is in effect at the time of final payment shall execute and deliver--

(i) An assignment to the Government, in form and substance satisfactory to the Contracting Officer, of refunds, rebates, credits, or other amounts (including interest, if any) properly allocable to costs for which the Contractor has been reimbursed by the Government under this contract; and

(ii) A release discharging the Government, its officers, agents, and employees from all liabilities, obligations, and claims arising out of or under this contract, except--

(A) Specified claims stated in exact amounts, or in estimated amounts when the exact amounts are not known;

(B) Claims (including reasonable incidental expenses) based upon liabilities of the Contractor to third parties arising out of the performance of this contract; provided, that the claims are not known to the Contractor on the date of the execution of the release, and that the Contractor gives notice of the claims in writing to the Contracting Officer within 6 years following the release date or notice of final payment date, whichever is earlier; and

(C) Claims for reimbursement of costs, including reasonable incidental expenses, incurred by the Contractor under the patent clauses of this contract, excluding, however, any expenses arising from the Contractor's indemnification of the Government against patent liability.

(End of clause)

52.216 -12 COST-SHARING CONTRACT--NO FEE (APR 1984)

(a) The Government shall not pay to the Contractor a fee for performing this contract.

(b) After paying $100,000.00 of the Government's share of the total estimated cost of performance shown in the Schedule, the Contracting Officer may withhold further payment of allowable cost until a reserve is set aside in an amount that the Contracting Officer considers necessary to protect the Government's interest. This reserve shall not exceed one percent of the Government's share of the total estimated cost shown in the Schedule or $100,000.00, whichever is less.

(End of clause)

52.217 -8 OPTION TO EXTEND SERVICES (NOV 1999)

The Government may require continued performance of any services within the limits and at the rates specified in the contract. These rates may be adjusted only as a result of revisions to prevailing labor rates provided by the Secretary of Labor. The option provision may be exercised more than once, but the total extension of performance hereunder shall not exceed 6 months. The Contracting Officer may exercise the option by written notice to the Contractor within 60 days.

(End of clause)

52.227 -11 PATENT RIGHTS--OWNERSHIP BY THE CONTRACTOR (MAY 2014)

(a) As used in this clause--

Invention means any invention or discovery that is or may be patentable or otherwise protectable under title 35 of the U.S. Code, or any variety of plant that is or may be protectable under the Plant Variety Protection Act (7 U.S.C. 2321, et seq.)

Made means--

(1) When used in relation to any invention other than a plant variety, the conception or first actual reduction to practice of the invention; or

(2) When used in relation to a plant variety, that the Contractor has at least tentatively determined that the variety has been reproduced with recognized characteristics.

Nonprofit organization means a university or other institution of higher education or an organization of the type described in section 501(c)(3) of the Internal Revenue Code of 1954 (26 U.S.C. 501(c)) and exempt from taxation under section 501(a) of the Internal Revenue Code (26 U.S.C. 501(a)), or any nonprofit scientific or educational organization qualified under a State nonprofit organization statute.

Practical application means to manufacture, in the case of a composition of product; to practice, in the case of a process or method; or to operate, in the case of a machine or system; and, in each case, under such conditions as to establish that the invention is being utilized and that its benefits are, to the extent permitted by law or Government regulations, available to the public on reasonable terms.

Subject invention means any invention of the Contractor made in the performance of work under this contract.

(b) Contractor's rights. (1) Ownership. The Contractor may retain ownership of each subject invention throughout the world in accordance with the provisions of this clause.

(2) License. (i) The Contractor shall retain a nonexclusive royalty-free license throughout the world in each subject invention to which the Government obtains title, unless the Contractor fails to disclose the invention within the times specified in paragraph (c) of this clause. The Contractor's license extends to any domestic subsidiaries and affiliates within the corporate structure of which the Contractor is a part, and includes the right to grant sublicenses to the extent the Contractor was legally obligated to do so at contract award. The license is transferable only with the written approval of the agency, except when transferred to the successor of that part of the Contractor's business to which the invention pertains.

(ii) The Contractor's license may be revoked or modified by the agency to the extent necessary to achieve expeditious practical application of the subject invention in a particular country in accordance with the procedures in FAR 27.302(i)(2) and 27.304 -1(f).

(c) Contractor's obligations. (1) The Contractor shall disclose in writing each subject invention to the Contracting Officer within 2 months after the inventor discloses it in writing to Contractor personnel responsible for patent matters. The disclosure shall identify the inventor(s) and this contract under which the subject invention was made. It shall be sufficiently complete in technical detail to convey a clear understanding of the subject invention. The disclosure shall also identify any publication, on sale (i.e., sale or offer for sale), or public use of the subject invention, or whether a manuscript describing the subject invention has been submitted for publication and, if so, whether it has been accepted for publication. In addition, after disclosure to the agency, the Contractor shall promptly notify the Contracting Officer of the acceptance of any manuscript describing the subject invention for publication and any on sale or public use.

(2) The Contractor shall elect in writing whether or not to retain ownership of any subject invention by notifying the Contracting Officer within 2 years of disclosure to the agency. However, in any case where publication, on sale, or public use has initiated the 1-year statutory period during which valid patent protection can be obtained in the United States, the period for election of title may be shortened by the agency to a date that is no more than 60 days prior to the end of the statutory period.

(3) The Contractor shall file either a provisional or a nonprovisional patent application or a Plant Variety Protection Application on an elected subject invention within 1 year after election. However, in any case where a publication, on sale, or public use has initiated the 1-year statutory period during which valid patent protection can be obtained in the United States, the Contractor shall file the application prior to the end of that statutory period. If the Contractor files a provisional application, it shall file a nonprovisional application within 10 months of the filing of the provisional application. The Contractor shall file patent applications in additional countries or international patent offices within either 10 months of the first filed patent application (whether provisional or nonprovisional) or 6 months from the date permission is granted by the Commissioner of Patents to file foreign patent applications where such filing has been prohibited by a Secrecy Order.

(4) The Contractor may request extensions of time for disclosure, election, or filing under paragraphs (c)(1), (c)(2), and (c)(3) of this clause.

(d) Government's rights--(1) Ownership. The Contractor shall assign to the agency, on written request, title to any subject invention--

(i) If the Contractor fails to disclose or elect ownership to the subject invention within the times specified in paragraph (c) of this clause, or elects not to retain ownership; provided, that the agency may request title only within 60 days after learning of the Contractor's failure to disclose or elect within the specified times.

(ii) In those countries in which the Contractor fails to file patent applications within the times specified in paragraph (c) of this clause; provided, however, that if the Contractor has filed a patent application in a country after the times specified in paragraph (c) of this clause, but prior to its receipt of the written request of the agency, the Contractor shall continue to retain ownership in that country.

(iii) In any country in which the Contractor decides not to continue the prosecution of any application for, to pay the maintenance fees on, or defend in reexamination or opposition proceeding on, a patent on a subject invention.

(2) License. If the Contractor retains ownership of any subject invention, the Government shall have a nonexclusive, nontransferable, irrevocable, paid-up license to practice, or have practiced for or on its behalf, the subject invention throughout the world.

(e) Contractor action to protect the Government's interest. (1) The Contractor shall execute or have executed and promptly deliver to the agency all instruments necessary to--

(i) Establish or confirm the rights the Government has throughout the world in those subject inventions in which the Contractor elects to retain ownership; and

(ii) Assign title to the agency when requested under paragraph (d) of this clause and to enable the Government to obtain patent protection and plant variety protection for that subject invention in any country.

(2) The Contractor shall require, by written agreement, its employees, other than clerical and nontechnical employees, to disclose promptly in writing to personnel identified as responsible for the administration of patent matters and in the Contractor's format, each subject invention in order that the Contractor can comply with the disclosure provisions of paragraph (c) of this clause, and to execute all papers necessary to file patent applications on subject inventions and to establish the Government's rights in the subject inventions. The disclosure format should require, as a minimum, the information required by paragraph (c)(1) of this clause. The Contractor shall instruct such employees, through employee agreements or other suitable educational programs, as to the importance of reporting inventions in sufficient time to permit the filing of patent applications prior to U.S. or foreign statutory bars.

(3) The Contractor shall notify the Contracting Officer of any decisions not to file a nonprovisional patent application, continue the prosecution of a patent application, pay maintenance fees, or defend in a reexamination or opposition proceeding on a patent, in any country, not less than 30 days before the expiration of the response or filing period required by the relevant patent office.

(4) The Contractor shall include, within the specification of any United States nonprovisional patent or plant variety protection application and any patent or plant variety protection certificate issuing thereon covering a subject invention, the following statement, “This invention was made with Government support under (identify the contract) awarded by (identify the agency). The Government has certain rights in the invention.”

(f) Reporting on utilization of subject inventions. The Contractor shall submit, on request, periodic reports no more frequently than annually on the utilization of a subject invention or on efforts at obtaining utilization of the subject invention that are being made by the Contractor or its licensees or assignees. The reports shall include information regarding the status of development, date of first commercial sale or use, gross royalties received by the Contractor, and other data and information as the agency may reasonably specify. The Contractor also shall provide additional reports as may be requested by the agency in connection with any march-in proceeding undertaken by the agency in accordance with paragraph (h) of this clause. The Contractor also shall mark any utilization report as confidential/proprietary to help prevent inadvertent release outside the Government. As required by 35 U.S.C. 202(c)(5), the agency will not disclose that information to persons outside the Government without the Contractor's permission.

(g) Preference for United States industry. Notwithstanding any other provision of this clause, neither the Contractor nor any assignee shall grant to any person the exclusive right to use or sell any subject invention in the United States unless the person agrees that any products embodying the subject invention or produced through the use of the subject invention will be manufactured substantially in the United States. However, in individual cases, the requirement for an agreement may be waived by the agency upon a showing by the Contractor or its assignee that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States, or that under the circumstances domestic manufacture is not commercially feasible.

(h) March-in rights. The Contractor acknowledges that, with respect to any subject invention in which it has retained ownership, the agency has the right to require licensing pursuant to 35 U.S.C. 203 and 210(c), and in accordance with the procedures in 37 CFR 401.6 and any supplemental regulations of the agency in effect on the date of contract award.

(i) Special provisions for contracts with nonprofit organizations. If the Contractor is a nonprofit organization, it shall--

(1) Not assign rights to a subject invention in the United States without the written approval of the agency, except where an assignment is made to an organization that has as one of its primary functions the management of inventions, provided, that the assignee shall be subject to the same provisions as the Contractor;

(2) Share royalties collected on a subject invention with the inventor, including Federal employee co-inventors (but through their agency if the agency deems it appropriate) when the subject invention is assigned in accordance with 35 U.S.C. 202(e) and 37 CFR 401.10;

(3) Use the balance of any royalties or income earned by the Contractor with respect to subject inventions, after payment of expenses (including payments to inventors) incidental to the administration of subject inventions for the support of scientific research or education; and

(4) Make efforts that are reasonable under the circumstances to attract licensees of subject inventions that are small business concerns, and give a preference to a small business concern when licensing a subject invention if the Contractor determines that the small business concern has a plan or proposal for marketing the invention which, if executed, is equally as likely to bring the invention to practical application as any plans or proposals from applicants that are not small business concerns; provided, that the Contractor is also satisfied that the small business concern has the capability and resources to carry out its plan or proposal. The decision whether to give a preference in any specific case will be at the discretion of the Contractor.

(5) Allow the Secretary of Commerce to review the Contractor's licensing program and decisions regarding small business applicants, and negotiate changes to its licensing policies, procedures, or practices with the Secretary of Commerce when the Secretary's review discloses that the Contractor could take reasonable steps to more effectively implement the requirements of paragraph (i)(4) of this clause.

(j) Communications.

(k) Subcontracts. (1) The Contractor shall include the substance of this clause, including this paragraph (k), in all subcontracts for experimental, developmental, or research work to be performed by a small business concern or nonprofit organization.

(2) The Contractor shall include in all other subcontracts for experimental, developmental, or research work the substance of the patent rights clause required by FAR Subpart 27.3.

(3) At all tiers, the patent rights clause must be modified to identify the parties as follows: references to the Government are not changed, and the subcontractor has all rights and obligations of the Contractor in the clause. The Contractor shall not, as part of the consideration for awarding the subcontract, obtain rights in the subcontractor's subject inventions.

(4) In subcontracts, at any tier, the agency, the subcontractor, and the Contractor agree that the mutual obligations of the parties created by this clause constitute a contract between the subcontractor and the agency with respect to the matters covered by the clause; provided, however, that nothing in this paragraph is intended to confer any jurisdiction under the Contract Disputes statute in connection with proceedings under paragraph (h) of this clause.

(End of clause)

52.243 -2 CHANGES--COST-REIMBURSEMENT (AUG 1987) - ALTERNATE I (APR 1984)

(a) The Contracting Officer may at any time, by written order, and without notice to the sureties, if any, make changes within the general scope of this contract in any one or more of the following:

(1) Description of services to be performed.

(2) Time of performance (i.e., hours of the day, days of the week, etc.).

(3) Place of performance of the services.

(b) If any such change causes an increase or decrease in the estimated cost of, or the time required for, performance of any part of the work under this contract, whether or not changed by the order, or otherwise affects any other terms and conditions of this contract, the Contracting Officer shall make an equitable adjustment in the (1) estimated cost, delivery or completion schedule, or both; (2) amount of any fixed fee; and (3) other affected terms and shall modify the contract accordingly.

(c) The Contractor must assert its right to an adjustment under this clause within 30 days from the date of receipt of the written order. However, if the Contracting Officer decides that the facts justify it, the Contracting Officer may receive and act upon a proposal submitted before final payment of the contract.

(d) Failure to agree to any adjustment shall be a dispute under the Disputes clause. However, nothing in this clause shall excuse the Contractor from proceeding with the contract as changed.

(e) Notwithstanding the terms and conditions of paragraphs (a) and (b) above, the estimated cost of this contract and, if this contract is incrementally funded, the funds allotted for the performance of this contract, shall not be increased or considered to be increased except by specific written modification of the contract indicating the new contract estimated cost and, if this contract is incrementally funded, the new amount allotted to the contract. Until this modification is made, the Contractor shall not be obligated to continue performance or incur costs beyond the point established in the Limitation of Cost or Limitation of Funds clause of this contract.

(End of clause)

52.243 -2 CHANGES--COST-REIMBURSEMENT (AUG 1987) - ALTERNATE V (APR 1984)

(a) The Contracting Officer may at any time, by written order, and without notice to the sureties, if any, make changes within the general scope of this contract in any one or more of the following:

(1) Drawings, designs, or specifications.

(2) Method of shipment or packing.

(3) Place of inspection, delivery, or acceptance.

(b) If any such change causes an increase or decrease in the estimated cost of, or the time required for, performance of any part of the work under this contract, whether or not changed by the order, or otherwise affects any other terms and conditions of this contract, the Contracting Officer shall make an equitable adjustment in the (1) estimated cost, delivery or completion schedule, or both; (2) amount of any fixed fee; and (3) other affected terms and shall modify the contract accordingly.

(c) The Contractor must assert its right to an adjustment under this clause within 30 days from the date of receipt of the written order. However, if the Contracting Officer decides that the facts justify it, the Contracting Officer may receive and act upon a proposal submitted before final payment of the contract.

(d) Failure to agree to any adjustment shall be a dispute under the Disputes clause. However, nothing in this clause shall excuse the Contractor from proceeding with the contract as changed.

(e) Notwithstanding the terms and conditions of paragraphs (a) and (b) above, the estimated cost of this contract and, if this contract is incrementally funded, the funds allotted for the performance of this contract, shall not be increased or considered to be increased except by specific written modification of the contract indicating the new contract estimated cost and, if this contract is incrementally funded, the new amount allotted to the contract. Until this modification is made, the Contractor shall not be obligated to continue performance or incur costs beyond the point established in the Limitation of Cost or Limitation of Funds clause of this contract.

(End of clause)

52.243 -7 NOTIFICATION OF CHANGES (APR 1984)

(a) Definitions.

"Contracting Officer," as used in this clause, does not include any representative of the Contracting Officer.

"Specifically authorized representative (SAR)," as used in this clause, means any person the Contracting Officer has so designated by written notice (a copy of which shall be provided to the Contractor) which shall refer to this subparagraph and shall be issued to the designated representative before the SAR exercises such authority.

(b) Notice. The primary purpose of this clause is to obtain prompt reporting of Government conduct that the Contractor considers to constitute a change to this contract. Except for changes identified as such in writing and signed by the Contracting Officer, the Contractor shall notify the Administrative Contracting Officer in writing, within 15 calendar days from the date that the Contractor identifies any Government conduct (including actions, inactions, and written or oral communications) that the Contractor regards as a change to the contract terms and conditions. On the basis of the most accurate information available to the Contractor, the notice shall state--

(1) The date, nature, and circumstances of the conduct regarded as a change;

(2) The name, function, and activity of each Government individual and Contractor official or employee involved in or knowledgeable about such conduct;

(3) The identification of any documents and the substance of any oral communication involved in such conduct;

(4) In the instance of alleged acceleration of scheduled performance or delivery, the basis upon which it arose;

(5) The particular elements of contract performance for which the Contractor may seek an equitable adjustment under this clause, including--

(i) What contract line items have been or may be affected by the alleged change;

(ii) What labor or materials or both have been or may be added, deleted, or wasted by the alleged change;

(iii) To the extent practicable, what delay and disruption in the manner and sequence of performance and effect on continued performance have been or may be caused by the alleged change;

(iv) What adjustments to contract price, delivery schedule, and other provisions affected by the alleged change are estimated; and

(6) The Contractor's estimate of the time by which the Government must respond to the Contractor's notice to minimize cost, delay or disruption of performance.

(c) Continued performance. Following submission of the notice required by (b) above, the Contractor shall diligently continue performance of this contract to the maximum extent possible in accordance with its terms and conditions as construed by the Contractor, unless the notice reports a direction of the Contracting Officer or a communication from a SAR of the Contracting Officer, in either of which events the Contractor shall continue performance; provided, however, that if the Contractor regards the direction or communication as a change as described in (b) above, notice shall be given in the manner provided. All directions, communications, interpretations, orders and similar actions of the SAR shall be reduced to writing and copies furnished to the Contractor and to the Contracting Officer. The Contracting Officer shall countermand any action which exceeds the authority of the SAR.

(d) Government response. The Contracting Officer shall promptly, within 15 calendar days after receipt of notice, respond to the notice in writing. In responding, the Contracting Officer shall either--

(1) Confirm that the conduct of which the Contractor gave notice constitutes a change and when necessary direct the mode of further performance;

(2) Countermand any communication regarded as a change;

(3) Deny that the conduct of which the Contractor gave notice constitutes a change and when necessary direct the mode of further performance; or

(4) In the event the Contractor's notice information is inadequate to make a decision under (1), (2), or (3) above, advise the Contractor what additional information is required, and establish the date by which it should be furnished and the date thereafter by which the Government will respond.

(e) Equitable adjustments.

(1) If the Contracting Officer confirms that Government conduct effected a change as alleged by the Contractor, and the conduct causes an increase or decrease in the Contractor's cost of, or the time required for, performance of any part of the work under this contract, whether changed or not changed by such conduct, an equitable adjustment shall be made--

(i) In the contract price or delivery schedule or both; and

(ii) In such other provisions of the contract as may be affected.

(2) The contract shall be modified in writing accordingly. In the case of drawings, designs or specifications which are defective and for which the Government is responsible, the equitable adjustment shall include the cost and time extension for delay reasonably incurred by the Contractor in attempting to comply with the defective drawings, designs or specifications before the Contractor identified, or reasonably should have identified, such defect. When the cost of property made obsolete or excess as a result of a change confirmed by the Contracting Officer under this clause is included in the equitable adjustment, the Contracting Officer shall have the right to prescribe the manner of disposition of the property. The equitable adjustment shall not include increased costs or time extensions for delay resulting from the Contractor's failure to provide notice or to continue performance as provided, respectively, in (b) and (c) above.

Note: The phrases “contract price” and “cost” wherever they appear in the clause, may be appropriately modified to apply to cost-reimbursement or incentive contracts, or to combinations thereof.

(End of clause)

52.244 -2 SUBCONTRACTS (OCT 2010) - ALTERNATE I (JUN 2007)

(a) Definitions. As used in this clause--

Approved purchasing system means a Contractor's purchasing system that has been reviewed and approved in accordance with Part 44 of the Federal Acquisition Regulation (FAR).

Consent to subcontract means the Contracting Officer's written consent for the Contractor to enter into a particular subcontract.

Subcontract means any contract, as defined in FAR Subpart 2.1, entered into by a subcontractor to furnish supplies or services for performance of the prime contract or a subcontract. It includes, but is not limited to, purchase orders, and changes and modifications to purchase orders.

(b) When this clause is included in a fixed-price type contract, consent to subcontract is required only on unpriced contract actions (including unpriced modifications or unpriced delivery orders), and only if required in accordance with paragraph (c) or (d) of this clause.

(c) If the Contractor does not have an approved purchasing system, consent to subcontract is required for any subcontract that--

(1) Is of the cost-reimbursement, time-and-materials, or labor-hour type; or

(2) Is fixed-price and exceeds--

(i) For a contract awarded by the Department of Defense, the Coast Guard, or the National Aeronautics and Space Administration, the greater of the simplified acquisition threshold or 5 percent of the total estimated cost of the contract; or

(ii) For a contract awarded by a civilian agency other than the Coast Guard and the National Aeronautics and Space Administration, either the simplified acquisition threshold or 5 percent of the total estimated cost of the contract.

(d) If the Contractor has an approved purchasing system, the Contractor nevertheless shall obtain the Contracting Officer's written consent before placing the following subcontracts: N/A

(e)(1) The Contractor shall notify the Contracting Officer reasonably in advance of placing any subcontract or modification thereof for which consent is required under paragraph (b), (c), or (d) of this clause, including the following information:

(i) A description of the supplies or services to be subcontracted.

(ii) Identification of the type of subcontract to be used.

(iii) Identification of the proposed subcontractor.

(iv) The proposed subcontract price.

(v) The subcontractor's current, complete, and accurate cost or pricing data and Certificate of Current Cost or Pricing Data, if required by other contract provisions.

(vi) The subcontractor's Disclosure Statement or Certificate relating to Cost Accounting Standards when such data are required by other provisions of this contract.

(vii) A negotiation memorandum reflecting--

(A) The principal elements of the subcontract price negotiations;

(B) The most significant considerations controlling establishment of initial or revised prices;

(C) The reason cost or pricing data were or were not required;

(D) The extent, if any, to which the Contractor did not rely on the subcontractor's cost or pricing data in determining the price objective and in negotiating the final price;

(E) The extent to which it was recognized in the negotiation that the subcontractor's cost or pricing data were not accurate, complete, or current; the action taken by the Contractor and the subcontractor; and the effect of any such defective data on the total price negotiated;

(F) The reasons for any significant difference between the Contractor's price objective and the price negotiated; and

(G) A complete explanation of the incentive fee or profit plan when incentives are used. The explanation shall identify each critical performance element, management decisions used to quantify each incentive element, reasons for the incentives, and a summary of all trade-off possibilities considered.

(2) If the Contractor has an approved purchasing system and consent is not required under paragraph (c), or (d) of this clause, the Contractor nevertheless shall notify the Contracting Officer reasonably in advance of entering into any (i) cost-plus-fixed-fee subcontract, or (ii) fixed-price subcontract that exceeds either the simplified acquisition threshold or 5 percent of the total estimated cost of this contract. The notification shall include the information required by paragraphs (e)(1)(i) through (e)(1)(iv) of this clause.

(f) Unless the consent or approval specifically provides otherwise, neither consent by the Contracting Officer to any subcontract nor approval of the Contractor's purchasing system shall constitute a determination--

(1) Of the acceptability of any subcontract terms or conditions;

(2) Of the allowability of any cost under this contract; or

(3) To relieve the Contractor of any responsibility for performing this contract.

(g) No subcontract or modification thereof placed under this contract shall provide for payment on a cost-plus-a-percentage-of-cost basis, and any fee payable under cost-reimbursement type subcontracts shall not exceed the fee limitations in FAR 15.404 -4(c)(4)(i).

(h) The Contractor shall give the Contracting Officer immediate written notice of any action or suit filed and prompt notice of any claim made against the Contractor by any subcontractor or vendor that, in the opinion of the Contractor, may result in litigation related in any way to this contract, with respect to which the Contractor may be entitled to reimbursement from the Government.

(i) The Government reserves the right to review the Contractor's purchasing system as set forth in FAR Subpart 44.3.

(j) Paragraphs (c) and (e) of this clause do not apply to the following subcontracts, which were evaluated during negotiations: N/A

(End of clause)

52.252 -2 CLAUSES INCORPORATED BY REFERENCE (FEB 1998)

This contract incorporates one or more clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. Also, the full text of a clause may be accessed electronically at this/these address(es):

http://farsite.hill.af.mil
www/usamraa.army.mil

(End of clause)

52.252 -6 AUTHORIZED DEVIATIONS IN CLAUSES (APR 1984)

(a) The use in this solicitation or contract of any Federal Acquisition Regulation (48 CFR Chapter 1) clause with an authorized deviation is indicated by the addition of "(DEVIATION)" after the date of the clause.

(b) The use in this solicitation or contract of any Federal Acquisition Regulation (48 CFR Chapter 1) clause with an authorized deviation is indicated by the addition of "(DEVIATION)" after the name of the regulation.

(End of clause)

252.225 -7043 ANTITERRORISM/FORCE PROTECTION POLICY FOR DEFENSE CONTRACTORS OUTSIDE THE UNITED STATES (MAR 2006)

(a) Definition. United States, as used in this clause, means, the 50 States, the District of Columbia, and outlying areas.

(b) Except as provided in paragraph (c) of this clause, the Contractor and its subcontractors, if performing or traveling outside the United States under this contract, shall--

(1) Affiliate with the Overseas Security Advisory Council, if the Contractor or subcontractor is a U.S. entity;

(2) Ensure that Contractor and subcontractor personnel who are U.S. nationals and are in-country on a non-transitory basis, register with the U.S. Embassy, and that Contractor and subcontractor personnel who are third country nationals comply with any security related requirements of the Embassy of their nationality;

(3) Provide, to Contractor and subcontractor personnel, antiterrorism/force protection awareness information commensurate with that which the Department of Defense (DoD) provides to its military and civilian personnel and their families, to the extent such information can be made available prior to travel outside the United States; and

(4) Obtain and comply with the most current antiterrorism/force protection guidance for Contractor and subcontractor personnel.

(c) The requirements of this clause do not apply to any subcontractor that is--

(1) A foreign government;

(2) A representative of a foreign government; or

(3) A foreign corporation wholly owned by a foreign government.

(d) Information and guidance pertaining to DoD antiterrorism/force protection can be obtained from HQDA-AT; telephone, DSN 222-9832 or commercial (703) 692-9832.

(End of clause)

Section J - List of Documents, Exhibits and Other Attachments

Exhibit/Attachment Table of Contents

DOCUMENT TYPE	DESCRIPTION	PAGES	DATE
Attachment 1	Quality Assurance Surveillance Plan	8	22-JUN-2015
Attachment 10	CDRL A009	2	26-MAR-2015
Attachment 11	CDRL A010	2	26-MAR-2015
Attachment 12	CDRL A011	2	26-MAR-2015
Attachment 13	CDRL A012	2	26-MAR-2015
Attachment 14	CDRL A013	2	26-MAR-2015
Attachment 2	CDRL A001	2	26-MAR-2015
Attachment 3	CDRL A002	2	26-MAR-2015
Attachment 4	CDRL A003	2	26-MAR-2015
Attachment 5	CDRL A004	2	26-MAR-2015
Attachment 6	CDRL A005	2	26-MAR-2015
Attachment 7	CDRL A006	2	26-MAR-2015
Attachment 8	CDRL A007	2	26-MAR-2015
Attachment 9	CDRL A008	2	26-MAR-2015

COVER SHEET

Master Cooperative Research and Development Agreement (CRADA)

[NOTE: This Cover Sheet is for internal management purposes only. It is not part of the Agreement and neither party is bound to anything contained in it]

Title: Collaboration to advance the Portable Neuromodulation Stimulator (PoNS™) device through FDA approval for assisted physical therapy in the treatment of soldiers and others with balance and gait disorder.

Effective Date:	1 February 2013	USAMRMC Control No. W81XWH-13-0145
Expiration Date:	31 December 2015	DA/TTPO Control No.

Primary NTIS Subject Code/Title:	334510 Electromedical and Electrotherapeutic Apparatus Manufacturing
Secondary NTIS Subject Code/Title:	N/A
STO Code/Title:	N/A
RAD:	USAMRMC CCCRP (RAD2)

Concurrence obtained from appropriate RAD/USSAMDA/CBMS-JPMO program managers: YES

Laboratories:

U.S. Army Medical Materiel Agency
693 Neiman Street
Fort Detrick, MD 21702-5001

U.S. Army Medical Materiel Development Activity
1430 Veterans Drive
Fort Detrick, MD 21702

Lab's Technical POCs:

Mr. Michael Husband for USAMMA
Phone: 301-619-4329
Email: michael.husband@amedd.army.mil

LTC David Shoemaker for USAMMDA
david.r.shoemaker@us.army.mil
301-619-7985

Lab's Legal Counsel:

Commander, U.S. Army Medical Research and Materiel Command
ATTN: MCMR-ZA-J (Mr. Jeremiah Kelly)
Fort Detrick, Frederick, MD 21701-5012
Voice Phone: (301) 619-6554 FAX Phone: (301) 619-5034

Company POC:

Mr. Philippe Deschamps
NeuroHabilitation Corporation
208 Palmer Alley, Newtown PA 18940
Phone: 614-596-2597
Email: pdeschamps409@gmail.com

Other Parties:

Advanced NeuroRehabilitation, LLC and its owners: Yuri P. Danilov, Mitchell E. Tyler, and Kurt A. Kaczmarek as inventors/background patent holders

Summary: Many soldiers in the Armed Forces suffer from balance and gait disorders subsequent to brain trauma from combat or other etiologies. Neuromodulation stimulation with the PoNS™ has been shown to aid in speeding up or increasing response to physical therapy in the treatment of vestibular disorder. The PoNS™ is presently an experimental device that has been successfully used in investigatory studies of human subjects with movement disorders. Further testing and design development are required to facilitate regulatory approval by the FDA and to meet the product requirements of its eventual end users.

A COOPERATIVE RESEARCH AND DEVELOPMENT AGREEMENT

Among
NeuroHabilitation Corporation (Cooperator)
Yuri P. Danilov, Mitchell E. Tyler, Kurt A. Kaczmarek (Background Patent Owners)
Advanced NeuroRehabilitation, LLC (Exclusive Licensee of Background Patent)

and

US Army Medical Materiel Agency (USAMMA)
a subordinate activity of the US Army Medical Research and Materiel Command (USAMRMC), in collaboration with the Combat Casualty Care Research Program (CCCRP)

and

US Army Medical Materiel Development Activity (USAMMDA)
(USAMMA and USAMMDA collectively as Laboratory)

Article 1 Background

1.00 This Agreement is entered into under the authority of the Federal Technology Transfer Act of 1986, 15 U.S.C. 3710a, et seq.

1.01 Laboratory, on behalf of the US Government, and Cooperator desire to cooperate in research and development of the Portable Neuromodulation Stimulator (PoNS™) assisted physical therapy for the treatment of soldiers with balance and gait disorder according to the attached Statement of Work (SOW) described in Appendix A. NOW, THEREFORE, the parties agree as follows with the understanding that the Background Patent Owners and Advanced NeuroRehabilitation, LLC, which holds an exclusive license to the background patent, are included in this Agreement only to the extent needed to fulfill responsibilities under Articles 8 and 9 and Appendix B:

Article 2 Definitions

2.00 The following terms are defined for this Agreement as follows:

2.01 "Agreement" means this Cooperative Research and Development Agreement (CRADA). The terms “Agreement” and “CRADA” are used interchangeably herein.

2.02 "Invention" and "Made" have the meanings set forth in Title 15 U.S.C. Section 3703(7) and (8).

2.03 "Proprietary Information" means information marked with a proprietary legend which embodies trade secrets developed at private expense or which is confidential business or financial information, provided that such information:

(i) is not generally known, or which becomes generally known or available during the period of this Agreement from other sources without obligations concerning their confidentiality;

(ii) has not been made available by the owners to others without obligation concerning its confidentiality;

(iii) is not already available to the receiving party without obligation concerning its confidentiality; and

(iv) is not independently developed by or on behalf of the receiving party, without reliance on the information received hereunder.

2.04 “Regulatory Application” means investigational new drug application (IND), investigational device exemption (IDE), new drug application (NDA), biologics license application (BLA), premarket approval application (PMA), or 510(k) pre-market notification filing, 510(k), or another regulatory filing submitted to the US Food and Drug Administration (FDA) related to a product or an analogous foreign filing. The related terms, “sponsor” and “applicant,” are used herein consistent with the definitions and/or usage found in 21 CFR §§3.2(c), 312.3, 600.3(t), 812.3(n), 812 Subpart C, and 814.20.

2.05 "Subject Data" means all recorded information first produced in the performance of this Agreement.

2.06 "Subject Invention" means any Invention Made as a consequence of, or in relation to, the performance of work under this Agreement.

Article 3 Research Scope and Administration

3.00 Statement of Work. Research performed under this Agreement shall be performed in accordance with the SOW incorporated as a part of this Agreement at Appendix A. It is agreed that any descriptions, statements, or specifications in the SOW shall be interpreted as goals and objectives of the services to be provided under this Agreement and not requirements or warranties. Laboratory and Cooperator will endeavor to achieve the goals and objectives of such services; however, each party acknowledges that such goals and objectives, or any anticipated schedule of performance, may not be achieved.

3.01 Review of Work. Periodic conferences shall be held between the parties for the purpose of reviewing the progress of work. It is understood that the nature of this research is such that completion within the period of performance specified, or within the limits of financial support allocated, cannot be guaranteed. Accordingly, all research will be performed in good faith.

3.02 Principal Investigator. Any work required by the Laboratory under the SOW will be performed under the supervision of Michael Husband of USAMMA (michael.husband@amedd.army.mil, 301-619-4329) and LTC David Shoemaker of USAMMDA (david.r.shoemaker@us.army.mil, 301-619-7985) or other duly appointed Army Principal Investigators (PIs) as may be designated for a given phase or task of the CRADA, who, as designated Army PIs have responsibility for the scientific and technical conduct of this project on behalf of their respective Laboratory. Any work required by the Cooperator under the SOW will be performed under the supervision of Mitchell E. Tyler, metyler1@wisc.edu, who has responsibility for the scientific and technical conduct of this project on behalf of the Cooperator.

3.03 Collaboration Changes. If at any time the co-PIs determine that the research, regulatory, or other data dictate a substantial change in the direction of the work, the parties shall make a good faith effort to agree on any necessary change to the SOW, obtain concurrences from the cognizant CCCRP Integrated Product Team (IPT) and/or working groups participating in the CRADA, and make the change by written notice to the addresses listed in section 13.05 Notices.

3.04 Final Report. The parties shall prepare a final report of the results of this project within six months after completing the SOW.

Article 4 Ownership and Use of Physical Property

4.00 Ownership of Materials or Equipment. All materials or equipment developed or acquired under this Agreement by the parties shall be the property of the party which developed or acquired the property, except that government equipment provided by Laboratory (1) which through mixed funding or mixed development must be integrated into a larger system, or (2) which through normal use at the termination of the Agreement has a salvage value that is less than the return shipping costs, shall become the property of Cooperator.

4.01 Use of Provided Materials. Both parties agree that any materials relating to them which were provided by one party to the other party will be used for research purposes only. Except as provided by Appendix B, the materials shall not be sold, offered for sale, used for commercial purposes, or be furnished to any other party without advance written approval from the provider's official signing this Agreement or from another official to whom the authority has been delegated, and any use or furnishing of material shall be subject to the restrictions and obligations imposed by this Agreement.

4.02 Notwithstanding the foregoing, it is acknowledged that the PoNS™ is functionally complete and subject to a pending patent application on behalf of the owner thereof and that Laboratory shall not, without the prior written consent of Cooperator, modify, improve, alter the PoNS™ or integrate it into any larger system. It is the intent of the parties to this Agreement that no ownership rights to the PoNS™ accrue to Laboratory in the performance, or by virtue of, this CRADA.

Article 5 Financial Obligation

5.00 In accordance with Section III of the SOW: Cooperator will be responsible for the cost of the ongoing design and development of the PoNS™ device to ensure its commercial availability post investigation and FDA clearance; and Laboratory will utilize government funds for the cost of research, testing and submissions as described at Section III(A) of the SOW. Articles 5.01 through 5.04 only apply in the event that the parties subsequently decide and mutually agree to use funds from Cooperator to cover some of the cost of Laboratory work under this CRADA.

5.01 Advance Payment. The performance of research by Laboratory under this Agreement may be conditioned on the advance payment by Cooperator of Laboratory's agreed upon costs for the performance of such research.

5.02 Deposit Account. In the event that funds from Cooperator are required for Laboratory performance of work under this CRADA, such funds shall be deposited in a specifically designated Department of the Army deposit account, details of which shall be provided if and when needed. The deposits shall be made by check or money order and shall be made payable to DFAS with proper information to identify this particular CRADA.

5.03 Insufficient and Excess Funds. Laboratory shall not be required to continue its research and development activities under this Agreement if the funds provided by Cooperator are insufficient to cover Laboratory's agreed upon costs for such continued activities. Funds not expended by Laboratory shall be returned to Cooperator upon Laboratory's submission of a final fiscal report to Cooperator.

5.04 Accounting Records. Laboratory shall maintain separate and distinct current accounts, records, and other evidence supporting all its expenditures under this Agreement. Laboratory shall provide Cooperator a semi-annual report accounting for the use of Cooperator's funds and a final fiscal report within four months after completing the SOW or ending its research activities under this Agreement. The accounts and records of Laboratory shall be available for reasonable inspection and copying by Cooperator and its authorized representative.

Article 6 Patent Rights

6.00 Reporting. The parties shall promptly report to each other all Subject Inventions reported to either party by its employees. All Subject Inventions Made during the performance of this Agreement shall be listed in the Final Report required by this Agreement.

6.01 Cooperator Employee Inventions. Laboratory waives any ownership rights the US Government may have in Subject Inventions Made by Cooperator employees and agrees that Cooperator shall have the option to retain title in Subject Inventions Made by Cooperator employees. Cooperator shall notify Laboratory promptly upon making this election and agrees to timely file patent applications on Cooperator's Subject Invention at its own expense. Cooperator agrees to grant to the US Government on Cooperator's Subject Inventions a nonexclusive, nontransferable, irrevocable, paid-up license in the patents covering a Subject Invention, to practice or have practiced, throughout the world by, or on behalf of the US Government. The nonexclusive license shall be evidenced by a confirmatory license agreement prepared by Cooperator in a form satisfactory to Laboratory.

6.02 Laboratory Employee Inventions. Laboratory shall have the initial option to retain title to, and file patent application on, each Subject Invention Made by its employees. The Laboratory agrees to grant an exclusive license to any invention arising under this Agreement to which it has ownership to the Cooperator in accordance with Title 15 U.S. Code Section 3710a, on terms negotiated in good faith. Any invention arising under this Agreement is subject to the retention by the US Government of nonexclusive, nontransferable, irrevocable, paid-up license to practice, or have practiced, the invention throughout the world by or on behalf of the US Government.

6.03 Joint Inventions. Any Subject Invention patentable under US patent law which is Made jointly by Laboratory employees and Cooperator employees under the Scope of Work of this Agreement shall be jointly owned by the parties. The parties shall discuss together a filing strategy and filing expenses related to the filing of the patent covering the Subject Invention. If a party decides not to retain its ownership rights to a jointly owned Subject Invention, it shall offer to assign such rights to the other party, pursuant to Paragraph 6.05, below. Any invention arising under this Agreement is subject to the retention by the US Government of nonexclusive, nontransferable, irrevocable, paid-up license to practice, or have practiced, the invention throughout the world by or on behalf of the US Government.

6.04 Government Contractor Inventions. In accordance with 37 Code of Federal Regulations 401.14, if one of Laboratory's Contractors conceives an invention while performing services at Laboratory to fulfill Laboratory's obligations under this Agreement, Laboratory may require the Contractor to negotiate a separate agreement with Cooperator regarding allocation of rights to any Subject Invention the Contractor makes, solely or jointly, under this Agreement. The separate agreement (i.e., between the Cooperator and the Contractor) shall be negotiated prior to the Contractor undertaking work under this Agreement or, with the Laboratory's permission, upon the identification of a Subject Invention. In the absence of such a separate agreement, the Contractor agrees to grant the Cooperator an option for a license in Contractor's inventions of the same scope and terms set forth in this Agreement for inventions made by Laboratory employees.

6.05 Filing of Patent Applications. The party having the right to retain title to, and file patent applications on, a specific Subject Invention may elect not to file patent applications, provided it so advises the other party within 90 days from the date it reports the Subject Invention to the other party. Thereafter, the other party may elect to file patent applications on the Subject Invention and the party initially reporting the Subject Invention agrees to assign its ownership interest in the Subject Invention to the other party.

6.06 Patent Expenses. The expenses attendant to the filing of patent applications shall be borne by the party filing the patent application. Each party shall provide the other party with copies of the patent applications it files on any Subject Invention, along with the power to inspect and make copies of all documents retained in the official patent application files by the applicable patent office. The parties agree to reasonably cooperate with each other in the preparation and filing of patent applications resulting from this Agreement.

6.07 Acknowledgement of Statement of Work. Nothing contained in this Article 6 is intended to alter or modify the provisions of Section 4.02 of this CRADA and/or the respective roles and responsibilities of the Laboratory and Cooperator as set forth in the SOW. It is acknowledged that it is not the intent or the expectation of the Parties that any Invention be Made pursuant to this Agreement.

Article 7 Exclusive License

7.00 Grant. The Laboratory agrees to grant to the Cooperator an exclusive license in each US patent application, and patents issued thereon, covering a Subject Invention, which is filed by the Laboratory subject to the reservation of a nonexclusive, nontransferable, irrevocable, paid-up license to practice and have practiced the Subject Invention on behalf of the United States.

7.01 Exclusive License Terms. The Cooperator shall elect or decline to exercise its right to acquire an exclusive license to any Subject Invention within six months of being informed by the Laboratory of the Subject Invention. The specific royalty rate and other terms of license shall be negotiated promptly in good faith and in conformance with the laws of the United States.

Article 8 Background Patent(s)

8.00 Laboratory Background Patent(s). Laboratory has filed patent application(s), or is the assignee of issued patent(s), listed below which contain(s) claims that are related to research contemplated under this Agreement. No license(s) to this/these patent applications or issue patents is/are granted under this Agreement, and this/these application(s) and any continuations to it/them are specifically excluded from the definitions of "Subject Invention" contained in this Agreement: None.

8.01 Cooperator Background Patent(s). Background Patent Owners warrant that they retain title to the patent application listed below, which contains claims that are related to research contemplated under this Agreement, such ownership obtained in accordance with the terms of a letter agreement with the National Institutes of Health, a fully executed copy of which will be provided to Laboratory. No license(s) to this/these patent applications or issue patents is/are granted under this Agreement, and this/these application(s) and any continuations to it/them are specifically excluded from the definitions of "Subject Invention" contained in this Agreement:

"Non-invasive neuromodulation (NINM) for rehabilitation of brain function," U.S. Patent Application number 12/348,301, filed 04 Jan 2009, by co-inventors Yuri P. Danilov, Mitchell E. Tyler, and Kurt A. Kaczmarek (collectively, Background Patent Owners). This patent application is licensed by the Background Patent Owners exclusively to Advanced NeuroRehabilitation, LLC, Madison, WI, which intends to license the patent application exclusively to Cooperator.

Article 9 Subject Data and Proprietary Information

9.00 Subject Data Ownership. Subject Data shall be jointly owned by the parties. Each party, upon request to the other party, shall have the right to review and to request delivery of all Subject Data, and delivery shall be made to the requesting party within two weeks of the request, except to the extent that such Subject Data are subject to a claim of confidentiality or privilege by a third party. If this Agreement is terminated, each Party agrees to provide the other with complete copies of all Subject Data within its possession.

9.01 Proprietary Information/Confidential Information. Each party shall place a proprietary notice on all information it delivers to the other party under this Agreement that it asserts is proprietary. The parties agree that any Proprietary Information or Confidential Information furnished by one party to the other party under this Agreement, or in contemplation of this Agreement, shall be used, reproduced and disclosed by the receiving party only for the purpose of carrying out this Agreement, which expressly includes clinical and commercial development of the PoNS^{TM}, and shall not be released by the receiving party to third parties unless consent to such release is obtained from the providing party.

9.02 Army Limited-Access Database. Notwithstanding anything to the contrary in this Article, the existence of established CRADAs specifying areas of research and their total dollar amounts may be documented on limited access, password-protected websites of the US Army Medical Research and Materiel Command (the parent organization of Laboratory), to provide the Command's leadership with a complete picture of military research efforts.

9.03 Laboratory Contractors. Cooperator acknowledges and agrees to allow Laboratory's disclosure of Cooperator's proprietary information to Laboratory's Contractors for the purposes of carrying out this Agreement. Laboratory agrees that it has or will ensure that its Contractors are under written obligation not to disclose Cooperator's proprietary information, except as required by law or court order (in which case the Laboratory shall give sufficient notice to Cooperator of any such application for a court order in order for Cooperator to take such steps as necessary to file opposition to such application), before Contractor employees have access to Cooperator's proprietary information under this Agreement.

9.04 Release Restrictions. Laboratory shall have the right to use all Subject Data for any Governmental purpose, but shall not release Subject Data publicly except: (i) Laboratory in reporting on the results of research may publish Subject Data in technical articles and other documents to the extent it determines to be appropriate; and (ii) Laboratory may release Subject Data where release is required by law or court order. The parties agree to confer prior to the publication of Subject Data to assure that no Proprietary Information is released and that patent rights are not jeopardized. Prior to submitting a manuscript for review which contains the results of the research under this Agreement, or prior to publication if no such review is made, each party shall be offered an ample opportunity to review any proposed manuscript and to file patent applications in a timely manner.

All publications will be provided to the Laboratory for review and sent to the US Army Medical Research and Materiel Command's Public Affairs Office (PAO) for review and approval prior to use or release. Per USAMRMC regulation, such PAO review will include operational security (OPSEC) review.

9.05 Public Affairs. As this work is or may have a high visibility, it is important that the same message be delivered to all stakeholders, including the public. Therefore, the parties agree that all releases of information related to this CRADA, to include press releases, shall be reviewed and approved by the USAMRMC PAO prior to release.

9.06 FDA Regulatory Matters. This Agreement involves a product subject to regulation by the U.S. Food and Drug Administration (FDA) for which FDA clearance or approval will be sought. Accordingly, the parties agree on the provisions described in Appendix B.

Article 10 Termination

10.00 Termination by Mutual Consent. Cooperator and Laboratory may elect to terminate this Agreement, or portions thereof, at any time by mutual consent.

10.01 Termination by Unilateral Action. Either party may unilaterally terminate this entire Agreement at any time by giving the other party written notice, not less than 30 days prior to the desired termination date.

10.02 Termination Procedures. In the event of termination, the parties shall specify the disposition of all property, patents and other results of work accomplished or in progress, arising from or performed under this Agreement by written notice. Upon receipt of a written termination notice, the parties shall not make any new commitments and shall, to the extent feasible, cancel all outstanding commitments that relate to this Agreement. Notwithstanding any other provision of this Agreement, any exclusive license entered into by the parties relating to this Agreement shall be simultaneously terminated unless the parties agree to retain such exclusive license.

Article 11 Disputes

11.00 Settlement. Any dispute arising under this Agreement which is not disposed of by agreement of the principal investigators shall be submitted jointly to the signatories of this Agreement. A joint decision of the signatories or their designees shall be the disposition of such dispute, however; nothing in this section shall prevent any party from pursuing any and all administrative and/or judicial remedies which may be allowable.

Article 12 Liability

12.00 Property. Except for a breach of the confidentiality provisions of Article 9, neither party shall be responsible for damages to any property provided to, or acquired by, the other party pursuant to this Agreement.

12.01 Cooperator's Employees. Cooperator agrees to indemnify and hold harmless the US Government for liability of any kind involving an employee of Cooperator arising in connection with this Agreement, and for all liabilities arising out of the use by Cooperator of Laboratory's research and technical developments, or out of any use, sale or other disposition by Cooperator of products made based on Laboratory's technical developments, except to the extent the liability is due to the negligence of Laboratory and actionable under the provisions of the Federal Tort Claims Act. This provision shall survive termination or expiration of this Agreement.

12.02 No Warranty. The parties make no express or implied warranty as to any matter whatsoever, including the conditions of the research or any Invention or product, whether tangible or intangible, Made, or developed under this agreement, or the ownership, merchantability, or fitness for a particular purpose of the research or any Invention or product.

Article 13 Miscellaneous

13.00 Governing Law. The construction, validity, performance, and effect of this Agreement shall be governed for all purposes by the laws applicable to the United States Government.

13.01 Export Control and Biological Select Agents and Toxins. The obligations of the parties to transfer technology to one or more other parties, provide technical information and reports to one or more other parties, and otherwise perform under this Agreement are contingent upon compliance with applicable United States export control laws and regulations. The transfer of certain technical data and commodities may require a license from a cognizant agency of the United States Government or written assurances by the Parties that the Parties shall not export technical data, computer software, or certain commodities to specified foreign countries without prior approval of an appropriate agency of the United States Government. The Parties do not, alone or collectively, represent that a license shall not be required, nor that, if required, it shall be issued. In addition, where applicable, the parties agree to fully comply with all laws, regulations, and guidelines governing biological select agents and toxins.

13.02 Independent Contractors. The relationship of the parties to this Agreement is that of independent contractors and not as agents of each other or as joint venturers or partners.

13.03 Use of Name or Endorsements. (a) The parties shall not use the name of the other party on any product or service which is directly or indirectly related to either this Agreement or any patent license or assignment agreement which implements this Agreement without the prior approval of the other party. (b) By entering into this Agreement, Laboratory does not directly or indirectly endorse any product or service provided, or to be provided, by Cooperator, its successors, assignees, or licensees. Cooperator shall not in any way imply that this Agreement is an endorsement of any such product or service. Press releases or other public releases of information shall be coordinated between the parties prior to release, except that the Laboratory may release the name of the Cooperator and the title of the research without prior approval from the Cooperator.

13.04 Survival of Specified Provisions. The rights specified in the following sections of this Agreement shall survive termination or expiration hereof:

i. 3.04
ii. 5.03
iii. 5.04
iv. Article 6
v. 7.00
vi. 9.00

vii. 9.03
viii. 9.04
ix. Article 12
x. Appendix B

13.05 Notices. All notices pertaining to or required by this Agreement shall be in writing and shall be signed by an authorized representative addressed as follows:

If to Cooperator:

Philippe Deschamps
208 Palmer Alley
Newtown, PA 18940
Phone: 614-596-2597
Email: pdeschamps409@gmail.com

If to Laboratory:

Michael Husband
Acute Care Division
Program Management Office Medical Devices USAMMA
693 Neiman Street
Fort Detrick, MD 21702

Any party may change such address by notice given to the other in the manner set forth above.

Article 14 Duration of Agreement and Effective Date

14.00 Effective Date. This Agreement shall enter into force as of the date it is signed by the last authorized representative of the parties.

14.01 Signature Execution. This Agreement may be executed in one or more counterparts by the parties by signature of a person having authority to bind the party, which may be by facsimile signature, each of which when executed and delivered, by facsimile transmission, mail, or email delivery, will be an original and all of which will constitute but one and the same Agreement.

14.02 Expiration Date. This Agreement will automatically expire on December 31, 2015 unless it is revised by written notice and mutual agreement.

[Signature Page Follows]

IN WITNESS WHEREOF, the Parties have caused this agreement to be executed by their duly authorized representatives as follows:

For the Cooperator:

DATE 1/22/13

Philippe Deschamps
Chief Operating Officer
NeuroHabilitation Corporation

For Advanced NeuroRehabilitation, LLC and as Background Patent Owners:

DATE 01/22/2013

Yuri P. Danilov

DATE 01/22/13

Mitchell E. Tyler

DATE 1/22/13

Kurt A. Kaczmarek

For the US Government USAMMA:

DATE 01 FEB '13

Alejandro Lopez-Duke
Colonel, Medical Service Corps
Commander, U.S. Army Medical Materiel Agency

For the US Government USAMMDA:

DATE 31 Jan 13

Russell E. Coleman
Colonel, Medical Service Corps
Commander, US Army Medical Materiel Development Activity

APPENDIX A

STATEMENT OF WORK

I. Title: Collaboration to advance the Portable Neuromodulation Stimulator (PoNS™) device through FDA approval for assisted physical therapy in the treatment of soldiers and others with balance and gait disorder.

II. Background: Current treatment methods for treating balance disorders typically involve medication and various forms of vestibular rehabilitation and physical therapy. Cooperator has developed a novel approach to rehabilitating the injured or diseased human brain using cranial nerve non-invasive neuromodulation (CN-NINM). Sustained application of this stimulation, in conjunction with exercises targeted on a functional deficit, appears to effect changes in activity, and therefore function, of these targeted brain structures. CN-NINM has been tested on subjects having balance, posture and gait disorders due to vestibular, cerebellar, or brainstem trauma. When applied in conjunction with other therapeutic interventions for sensory and movement control, integrating CN-NINM has been demonstrated to create localized functional changes in brain activity levels which, along with observed improvements in balance, posture, gait and limb movement control, provides evidence of functional neurorehabilitation.

Many soldiers in the Armed Forces suffer from balance and gait disorders subsequent to brain trauma from combat or other etiologies. Neuromodulation stimulation with the PoNS™ has been shown to aid in speeding up or increasing response to physical therapy in the treatment of vestibular disorder. The PoNS™ is presently an experimental device that has been successfully used in investigatory studies of human subjects with movement disorders. Further testing and design development are required to facilitate regulatory approval by the FDA and to meet the product requirements of its eventual end users. An efficiently mass produced PoNS™ that suffers no decreased functionality or reliability could allow patients to regain normal activity in their civilian life, and for some, could allow them to return more quickly to their duty station or military mission.

The goal of this Agreement is to investigate, through the means of a blinded, well-designed study, to determine if the PoNS™ can be mass produced and deployed in a prototypical clinical setting without suffering any decreased functionality or reliability, and demonstrating safety and efficacy in a registrational clinical trial.

Related background intellectual property includes the trademark, PoNS™, a pending U.S. patent application as cited in Article 8.01, the current PoNS™ prototype design, and proprietary physical therapy protocols developed by scientists at the University of Wisconsin at Madison.

III. Collaboration**:**

A. Subject to the availability of government funds to cover Laboratory costs, Laboratory agrees to:

1. Serve as the Regulatory Sponsor of the PoNS™ for all formal and informal interactions with the FDA necessary to gain FDA clearance/approval, to include the initial 513(g) submission.
2. Supply the facilities and personnel to execute and/or oversee the execution of clinical studies of the device for FDA clearance/approval in support of an intended use of the PoNS™ for the treatment of soldiers suffering from balance and gait disorders.
   - i. Provide clinical trial monitoring
   - ii. Provide full biostatical support
   - iii. Provide data management oversight
   - iv. Provide product technical oversight
   - v. Provide safety pharmacovigilance and reporting to FDA
   - vi. Device qualification/validation;

vii. Testing plan for release of devices;

3. Conduct assessments of manufacturing facility and assist/advise facility in meeting FDA manufacturing requirements.
4. Aid in designing the clinical protocols to study the PoNS™ device as an adjunct to specialized physical therapy in patients with balance and gait disorders.
5. Provide advice and expertise on all Army administrative protocols and approvals to execute the studies with military personnel, reservists, and/or veterans.
6. Prepare and submit the necessary regulatory filings for FDA to secure regulatory clearance or approval, after which such clearance/approval will be transferred to Cooperator.
7. Ensure Cooperator receives copies of all formal and informal communications with FDA related to the PoNS™ device.

B. Subject to the availability of funds to cover Cooperator costs, Cooperator agrees to:

1. Complete the commercial design, including ergonomics (e.g. user controls, comfort), and design for improved manufacturability, reliability, and field support and regulatory testing to comply with the FDA regulations for such devices.
2. Work collaboratively with the Laboratory and other Army personnel to supply all the technical specifications, documentation and any other information required to address FDA requests on the pathway to obtaining FDA clearance/approval of the PoNS™ device.
3. Finalize the commercial design of the PoNS™ device so that the devices would be commercially available to the Army should the results of the study be positive.
4. Identify and engage a commercial manufacturer post-FDA clearance of the device to produce the device for purchase of the Government.
5. Provide expertise and training in the design of clinical study protocols.
6. Provide expertise and training of Army and/or Veterans Affairs personnel in the physical therapy interventions required for clinical studies.

This SOW may be adjusted by the parties in accordance with Article 3.03 of the Agreement.

APPENDIX B

GOVERNMENT RIGHTS TO ENSURE PRODUCT AVAILABILITY

This Appendix B only applies in the event that Cooperator is not able or willing to commercialize the subject technology within a reasonable period of time as defined herein from the expiration or termination of the CRADA.

The terms “Regulatory Application” and “sponsor” and “applicant” are used herein as defined in 2.04 of this Agreement. The term “subject technology” is used herein to mean the PoNS™ technology as described U.S. Patent Application number 12/348,301 as well as any improvements or modifications developed during the term of this CRADA.

The parties to this CRADA further agree as follows:

1. USAMRMC will be the sponsor of the Regulatory Application described in this Agreement until said application is cleared or approved by the FDA, at which point USAMRMC will transfer such clearance or approval to Cooperator.

2. During USAMRMC sponsorship, Laboratory will provide Cooperator, upon request, all communication, both formal and informal, to or from the FDA regarding the subject technology being developed under this CRADA. In addition, Laboratory will ensure that Cooperator staff are permitted the opportunity to participate in any sponsor meetings, both formal and informal, in which the subject technology is discussed with the FDA.

3. After any transfer of the Regulatory Application from USAMRMC to Cooperator, and in the event that Cooperator fails to obtain any additional, required FDA approval or clearance or to satisfy any outstanding regulatory requirement due from the sponsor within two (2) years after the expiration or termination of this CRADA, or where the Cooperator fails to commercially market the regulated technology to the point where the US Government may purchase the technology within two (2) years after the expiration or termination of this CRADA, Cooperator will:

    a. transfer possession, ownership and sponsorship/holdership of any Regulatory Application, regulatory correspondence, and supporting regulatory information related to the subject technology to USAMRMC;

    b. inform FDA of the transfer of sponsorship or holdership of the Regulatory Application transferred under section 3a above; and

    c. provide the U.S. Government with a non-exclusive, paid-up, irrevocable license to any patent, copyright, data rights, proprietary information (as defined in section 2.03) or regulatory information held by the Cooperator, or obtained from the Cooperator by a third party, in order to permit the U.S. Government to pursue commercialization of the subject technology.

NOTICE OF MODIFICATION No. 1
of
COOPERATIVE RESEARCH AND DEVELOPMENT AGREEMENT
between

US Army Medical Materiel Agency (USAMMA)
a subordinate activity of the US Army Medical Research and Materiel Command (USAMRMC), in collaboration with the Combat Casualty Care Research Program (CCCRP)

and

US Army Medical Materiel Development Activity (USAMMDA)
(USAMMA and USAMMDA collectively as Laboratory)

and

NeuroHabilitation Corporation (Cooperator)
Yuri P. Danilov, Mitchell E. Tyler, Kurt A. Kaczmarek (Background Patent Owners)
Advanced NeuroRehabilitation, LLC (Exclusive Licensee of Background Patent)

The **United States Army Medical Materiel Agency**, 693 Neiman St, Fort Detrick, Maryland 21702-5012, U.S.A.; **United States Army Medical Materiel Development Activity**, 1430 Veterans Drive, Fort Detrick, Maryland 21702-5012, U.S.A. and **NeuroHabilitation Corporation** 208 Palmer Alley, Newtown, PA 18940, entered into a Cooperative Research and Development Agreement ("Agreement") (U.S. Army Medical Research and Materiel Command Control Number W81XWH-13-0145) on 1 February 2013, for research and development on "Collaboration to advance the Portable Neuromodulation Stimulator (PoNS™) device through FDA approval for assisted physical therapy in the treatment of soldiers and others with balance and gait disorder."

The Parties agree that two of the tasks listed under Section III-B of the CRADA Statement of Work (SOW) were inadvertently included in the scope of this CRADA.

Now, the Parties desire to amend the Agreement as follows:

1. Delete tasks 5 and 6 of Section III-B of the SOW.

2. Replace the PIs of both USAMMA and USAMMDA to now read:
   3.02 Principal Investigator. Any work required by the Laboratory under the SOW will be performed under the supervision of Scott Colmyer of USAMMA (scott.d.colmyer.civ@mail.mil, 301-619-6982) and Dr. Robert Miller of USAMMDA (robert.e.miller325.civ@mail.mil, 301-619-0317)...

3. Change the contact information for notices to be sent to Laboratory to now read:
   13.05 Notices. All notices pertaining to or required...
   If to Laboratory:
   Scott Colmyer
   Medical Materiel Solutions
   Program Management Office Medical Devices USAMMA
   693 Neiman Street
   Fort Detrick, MD 21702

4. Advanced NeuroRehabilitation, LLC will share all data with USAMMA.
5. NeuroHabilitation Corporation will provide all data supporting clinical claims for regulatory approval.
6. Add to following tasks to the SOW under USAMMDA agrees to:

Provide regulatory support as agreed upon for unregulated Studies. The associated budgets and funding reimbursement will be reviewed and agreed upon between USAMMA and USAMMDA.

All other provisions of this Agreement, as previously amended, are unchanged.
IN WITNESS WHEREOF, the Parties have caused this modification to be executed by their duly authorized representatives as follows:

For the Cooperator:

DATE 4/26/2014

Philippe Deschamps
Chief Operating Officer
NeuroHabilitation Corporation

For Advanced NeuroRehabilitation, LLC and as Background Patent Owners:

DATE 04/24/2014

Yuri P. Danilov

DATE 2014.04.24

Mitchell E. Tyler

DATE 4/24/2014

Kurt A. Kaczmarek

For the US Government USAMMA:

DATE 4/29/2014

Alejandro Lopez-Duke
Colonel, Medical Service Corps
Commander, U.S. Army Medical Materiel Agency

For the US Government USAMMDA:

DATE 4/28/2014

Stephen J. Dalal
Colonel, Medical Service Corps
Commander, US Army Medical Materiel Development Activity

NOTICE OF MODIFICATION No. 2
of
COOPERATIVE RESEARCH AND DEVELOPMENT AGREEMENT
between

US Army Medical Materiel Agency (USAMMA)
a subordinate activity of the US Army Medical Research and Materiel Command (USAMRMC), in collaboration with the Combat Casualty Care Research Program (CCCRP)

and

US Army Medical Materiel Development Activity (USAMMDA)
(USAMMA and USAMMDA collectively as Laboratory)

and

NeuroHabilitation Corporation (Cooperator)
Yuri P. Danilov, Mitchell E. Tyler, Kurt A. Kaczmarek (Background Patent Owners)
Advanced NeuroRehabilitation, LLC (Exclusive Licensee of Background Patent)

The **United States Army Medical Materiel Agency**, 693 Neiman St. Fort Detrick, Maryland 21702-5012, U.S.A.; **United States Army Medical Materiel Development Activity**, 1430 Veterans Drive, Fort Detrick, Maryland 21702-5012, U.S.A. and **NeuroHabilitation Corporation** 208 Palmer Alley, Newtown, PA 18940, entered into a Cooperative Research and Development Agreement ("Agreement") (U.S. Army Medical Research and Materiel Command Control Number W81XWH-13-0145) on 1 February 2013, for research and development on "Collaboration to advance the Portable Neuromodulation Stimulator (PoNS™) device through FDA approval for assisted physical therapy in the treatment of soldiers and others with balance and gait disorder."

The Parties agree that a modification is required to the agreement to better align with current objectives of the collaboration.

Now, the Parties desire to amend the Agreement as follows:

- Appendix A. Section III A and B are changed to reflect the following:
  - The role of Regulatory Sponsor and executor of FDA-regulated studies in the pursuit of the original indication sought under this agreement (balance and gait disorder) has been shifted from the Laboratory to the Cooperator;
  - The original indication (balance and gait disorder) is removed from the Statement of Work and replaced with "military relevant neurological disorders, including but not limited to Tinnitus, PTSD, pain and any subsequent indications identified by the parties";
  - The Cooperator will be the Regulatory Sponsor for all future indications governed by this CRADA;
  - The Laboratory will be responsible for supporting the execution of studies using the PoNS device as a treatment for mutually agreed-upon military relevant neurological disorders, including but not limited to Tinnitus, PTSD, pain and any subsequent indications identified by the parties; and
  - The Cooperator will be responsible for the supply of devices in support of mutually agreed upon studies governed by this CRADA.

- Appendix B.
    - Appendix B applies for any mutually agreed-upon military-relevant neurological disorders governed by the CRADA. Once the parties have mutually agreed that a neurological disorder is military relevant, as documented in any written communication between the parties, the terms and conditions of Appendix B apply and cannot be unilaterally modified or unilaterally rescinded;
    - Section 1 is modified for reflect the role of FDA sponsor is the responsibility of the Cooperator;
    - Section 2 is modified to require all FDA communication to be shared with Laboratory;
    - Section 3 is modified to extend from two (2) to four (4) years the time for Cooperator to obtain final regulatory approval or clearance. This extension to four (4) years is only in the event that a pre-market approval application (PMA) is required for the following PoNS indication: "aid to therapy for chronic balance deficits resulting from mild to moderate TBI." This clause remains unchanged as it relates to other indications governed by this agreement.
    - Section 3 is modified to extend from two (2) to four (4) years the timeframe for commercialization of the product. This clause remains unchanged as it relates to other indications governed by this agreement.

All other provisions of this Agreement, as previously amended, are unchanged.
IN WITNESS WHEREOF, the Parties have caused this modification to be executed by their duly authorized representatives as follows:

For the Cooperator:

/s/ Philippe Deschamps DATE 12/22/2014
Philippe Deschamps
Chief Operating Officer
NeuroHabilitation Corporation

For Advanced NeuroRehabilitation, LLC and as Background Patent Owners:

/s/ Yuri P. Danilov DATE 26 DEC 2014
Yuri P. Danilov

/s/ Mitchell E. Tyler DATE 22 DEC 2014
Mitchell E. Tyler

/s/ Kurt A. Kaczmarek DATE 26 DEC 2014
Kurt A. Kaczmarek

For the US Government USAMMA:

/s/ David Gibson DATE
Colonel, Medical Service Corps
Commander, U.S. Army Medical Materiel Agency

For the US Government USAMMDA:

/s/ Stephen J. Dalal DATE 12 JAN 15
Stephen J. Dalal
Colonel, Medical Service Corps
Commander, U.S. Army Medical Materiel Development Agency

NOTICE OF MODIFICATION No. 3
of
COOPERATIVE RESEARCH AND DEVELOPMENT AGREEMENT
between

US Army Medical Materiel Agency (USAMMA)
a subordinate activity of the US Army Medical Research and Materiel Command (USAMRMC), in collaboration with the Combat Casualty Care Research Program (CCCRP)

and

US Army Medical Materiel Development Activity (USAMMDA)
(USAMMA and USAMMDA collectively as Laboratory)

and

NeuroHabilitation Corporation (Cooperator)
Yuri P. Danilov, Mitchell E. Tyler, Kurt A. Kaczmarek (Background Patent Owners)
Advanced NeuroRehabilitation, LLC (Exclusive Licensee of Background Patent)

The **United States Army Medical Materiel Agency**, 693 Neiman St, Fort Detrick, Maryland 21702-5012, U.S.A.; **United States Army Medical Materiel Development Activity**, 1430 Veterans Drive, Fort Detrick, Maryland 21702-5012, U.S.A. and **NeuroHabilitation Corporation** 208 Palmer Alley, Newtown, PA 18940, entered into a Cocperative Research and Development Agreement ("Agreement") (U.S. Army Medical Research and Materiel Command Control Number W81XWH-13-0145) on 1 February 2013, for research and development on "Collaboration to advance the Portable Neuromodulation Stimulator (PoNS™) device through FDA approval for assisted physical therapy in the treatment of soldiers and others with balance and gait disorder."

The Parties agree that a modification is required to the agreement to better align with current objectives of the collaboration. .

Now, the Parties desire to amend the Agreement as follows:

- Article 3 Section 02 is changed to reflect the following:
  - Laboratory Principal Investigator is changed from Mr Scott Colmyer to Mr Brian Dacanay, 693 Neiman St, Fort Detrick, MD 21702, 301-619-4348, 301-619-9422, brian.i.dacanay.civ@mail.mil
- Article 14 Section 03 is changed to reflect the following:
  - Renewal: Expiration date will be an additional 2 years, to December 31, 2017 unless revised by written notice and mutual agreement.

All other provisions of this Agreement, as previously amended, are unchanged.
IN WITNESS WHEREOF, the Parties have caused this modification to be executed by their duly authorized representatives as follows:

For the Cooperator:

Philippe Deschamps
Chief Operating Officer
NeuroHabilitation Corporation

DATE 12/13/15

For Advanced NeuroRehabilitation, LLC and as Background Patent Owners:

Yuri P. Danilov

DATE 12/02/2015

Mitchell E. Tyler

DATE 05 DEC 2015

Kurt A. Kaczmarek

DATE 12/11/2015

For the US Government USAMMA:

David Gibson
Colonel, Medical Service Corps
Commander, U.S. Army Medical Materiel Agency

DATE 28 DEC 15

For the US Government USAMMDA:

William E. Geesey
Colonel, Medical Service Corps
Commander, US Army Medical Materiel Development Activity

DATE 22 DEC 2015

HELIUS MEDICAL TECHNOLOGIES AND U.S. ARMY EXTEND SOLE SOURCE CONTRACT FOR THE PONS™ DEVICE TESTING AND DEVELOPMENT

(Newtown, PA) – November 21, 2016 - Helius Medical Technologies, Inc. (TSX: HSM) (OTCQB: HSDT) ("Helius" or the "Company") announced that NeuroHabilitation Corporation ("NHC"), a division of Helius, successfully executed an amendment to the sole source cost sharing contract entered into with the U.S. Army Medical Research and Materiel Command (USAMRMC). The contract is extended to December 31, 2017 and allows Helius to include additional study sites for the clinical trial investigating the safety and effectiveness of the Portable Neuromodulation Stimulator (PoNS™) for the treatment of chronic balance deficits in subjects with mild to moderate traumatic brain injury (mTBI).

"Extending this contract reflects a continued commitment from the USAMRMC and Helius to address the large unmet clinical need represented by both civilian and military patients suffering from chronic symptoms of traumatic brain injury," said Helius CEO, Phil Deschamps.

About the PoNS™

The Portable Neuromodulation Stimulator (PoNS) device is an investigational medical device being studied for the treatment of neurological symptoms caused by disease or trauma. The PoNS is currently being studied in the United States and Canada for the treatment of chronic balance deficits in subjects with mTBI.

The PoNS device is a non-invasive means for delivering neurostimulation through the tongue. Researchers believe that use of the tongue as a gateway to the brain may be one of the most natural, non-invasive and direct ways to stimulate the brain. The tongue is anatomically unique, being richly innervated by thousands of nerve fibers and interconnected to the brainstem by two major cranial nerves.

About Helius Medical Technologies (HMT)

Helius Medical Technologies is a medical technology company focused on neurological wellness. HMT seeks to develop, license and acquire unique and non-invasive platform technologies that amplify the brain's ability to heal itself. HMT intends to file for U.S. Food and Drug Administration clearance for the PoNS™ device. For more information, please visit www.heliusmedical.com.

The contents of this website are not, and should be deemed to be, incorporated by reference herein.

The Canadian Securities Exchange has not reviewed and does not accept responsibility for the adequacy or accuracy of the content of this press release.

Cautionary Disclaimer Statement:

This press release contains forward-looking statements relating to the results of the Company's registrational clinical trial, FDA submission process, planned future commercial distribution, and other statements that are not historical facts. Forward-looking statements are often identified by terms such as "will", "may", "should", "anticipate", "expects" and similar expressions. All statements other than statements of historical fact, included in this release are forward-looking statements that involve risks and uncertainties. There can be no assurance that such statements will prove to be accurate and actual results and future events could differ materially from those anticipated in such statements. Important factors that could cause actual results to differ materially from the Company's expectations include the failure to satisfy the conditions of the Securities and Exchange Commission and the Canadian Securities Exchange, the success of the Company's business plan, availability of funds, government regulations, operating costs, the Company's ability to achieve revenues and other risks detailed from time to time in the filings made by the Company with its securities regulators.

The reader is cautioned that assumptions used in the preparation of any forward-looking information may prove to be incorrect. Events or circumstances may cause actual results to differ materially from those predicted, as a result of numerous known and unknown risks, uncertainties, and other factors, many of which are beyond the control of the Company. Many factors may cause the Company's actual results to differ materially from any forward-looking statement. The reader is cautioned not to place undue reliance on any forward-looking information. Such information, although considered reasonable by management at the time of preparation, may prove to be incorrect and actual results may differ materially from those anticipated. Forward-looking statements contained in this press release are expressly qualified by this cautionary statement. The forward-looking statements contained in this press release are made as of the date of this press release and the Company undertakes no obligation to update or revise publicly this press release to reflect events or circumstances after the date hereof, except as required by applicable law.

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