UNIVERSITY MEDICAL CENTER OF SOUTHERN NEVADA
RFP NO. 2011-09
Cochlear Implant Products

March 3, 2011

ADDENDUM NO. 1

Exhibit D – Sample Agreement
Exhibit D – Sample Agreement shall be deleted in its entirety and replace with the attached Sample Agreement (rev 3/1/11).

Disclosure of Ownership Form
The Disclosure of Ownership form shall be deleted in its entirety and replace with the attached Disclosure of Ownership form (rev 3/1/11).

The RFP Opening date of March 9, 2011; 2:00:00 p.m. remains unchanged.

Should you have any questions, please contact me at (702) 383-3606 or via email at jim.haining@umcsn.com.

Issued by:

Jim Haining, CPSM, C.P.M., A.P.P., CPSD
Contracts Management

Attachment(s): Exhibit D – Sample Agreement (rev 3/1/11)
Disclosure of Ownership Form (rev 3/1/11)

Sample Agreement
University Medical Center of Southern Nevada
Cochlear Implant Product Agreement

By placing any spinal implant product at University Medical Center of Southern Nevada (UMC), Supplier agrees to this Agreement and will abide by the specifications outlined in this Agreement. This Agreement is not exclusive to Supplier and UMC may have many agreements for the products.

1. Products

a. All products (both implants and surgical instruments) placed on-site at UMC will be on consignment only. Supplier may choose to deliver product as requested in lieu of consignment. Supplier will provide an itemized list of all consigned products placed on-site.
b. Supplier will retain title to all products until such time as this Agreement provides for transfer of title to UMC.
c. UMC will be responsible for proper storage conditions, security and inventory management (e.g., using product closest to expiration before other product of same type and size) for all consignment product received in its custody or under its control. UMC will ensure that consignment product is covered by its fire, theft and/or other applicable insurance policies.
d. For consigned products only, legal title to products maintained in UMC's stocking area and under UMC's control shall remain with Supplier until removed from UMC's stocking area for use by UMC. UMC shall have sole physical control and responsibility for product received by UMC and, therefore, UMC shall bear the risk of loss and costs to replace such products in the event of loss or damage of products. Legal title to a product will transfer to UMC at the time the product inner package is opened, or the product is lost, damaged or otherwise rendered unsalable while in UMC's custody or control (a "Use"). Expired Product will not be considered a Use by UMC under this Agreement. If UMC discovers expired product under its control, it will immediately pull and quarantine that product and contact Supplier representative for replacement product at no cost to UMC.
e. For each Use of a product, UMC will issue a purchase order for that product as noted in the procedures of Section 7, below, and UMC will be invoiced at the then-current contract price. Supplier will then provide UMC with a replacement product on consignment, and title to the replacement product will remain with Supplier until used.
f. Any implant restocking, additions, and/or replacements will be coordinated with UMC Surgical Services Materials Manager or his designee.
g. Access to these consigned sets will be coordinated with UMC Surgical Services Materials Manager or his designee.
h. All products must be approved by the UMC Surgical Services/Implant Product Committee prior to placement and use. Failure to get prior approval will result in non-payment for the product(s) and the supplier representative's privileges/credentialing at UMC may be suspended. Continued violation of this process can result in credentialing revocation.
i. UMC Sterile Processing Department Policy #107 "Loaned/Consigned Instrument Trays, Receiving, Decontamination & Vendor Requirements (Exhibit B) is incorporated into this Agreement by reference.

2. Upgrading Sets

In the event that product or instrumentation require upgrading, Supplier will trade out the current product at no charge. This includes both opened and unopened product. UMC expects to have the newest technology available and expects timely trade outs.

3. New Technology

a. New technology is defined as a significant material or function change of an existing product and/or line of products.
b. Product redesign or refinement does not constitute a new technology.
c. All new innovative and revolutionary technologies must be approved by the UMC Surgical Services/Implant Product Committee PRIOR TO THE CASE. Devices brought into the operating room without prior approval will be at no charge to UMC or the patient and the Supplier representative's privileges/credentialing at UMC may be suspended. Continued violation of this process can result in credentialing revocation.
d. UMC Surgical Services/Implant Product Committee will determine if the new technology is acceptable for use at UMC after the product has been used in a pre-determined number of cases conducted at UMC (minimum of 5 cases) at the current pricing schedule.
e. Pricing for new technology will be negotiated after acceptance by the UMC Surgical Services/Implant Product Committee.

4. Expiration of Product

Supplier will ensure that expired products will be removed from consigned stock prior to the expiration date on the products and will never be used in any case. Supplier will not bring an expired product into the hospital for any reason. Violation of this process can result in credentialing revocation.

5. Disposable Products

If the supplier requires the use of disposable products for placement of the product, pricing will be negotiated at no less than 40% off the nationally published list price. This must be completed PRIOR to the use of the products and coordinated with UMC Surgical Services Materials Manager or his designee.

6. Freight / Shipping

a. All products will be shipped FOB Destination, freight included.
b. No Shipping / Handling or Freight charges will be paid by UMC for products delivered directly to the facility by supplier's representative.
c. Utilization of UMC Supplier Packing List documentation must be completed by supplier's representative within 24 hours of procedure completion and be accompanied with a bill of lading from supplier to include:
   i. UMC Supplier Packing List
      1. Item quantity, price per unit, catalog re-order number, complete description including size, extended line costs, extended cost total
      2. Patient ID Label, Case Circulating Nurse signature, date of surgery, surgeon name, case room number
      3. Supplier's complete name, address, and contact information (both email / phone)
      4. Manufacturer's complete name, address, and contact information if applicable
   ii. Supplier's Bill of Lading must include:
      1. Manufacturer's complete name, address, and contact information
      2. Supplier's complete name, address, and contact information (both email / phone)
      3. Item quantity, price per unit, catalog re-order number, complete description including size, extended line costs, extended cost total
      4. Patient ID Label, Case Circulating Nurse signature, date of surgery, surgeon name, case room number

7. Invoicing / Purchase Orders

Purchase orders are provided based on the completion and timeliness of the UMC Universal Vendor Packing Slip and Company Packing List as listed below and will be issued after Use of the product:

1. Patient Sticker on all documents
2. Circulating Nurse signature and date on all documents
3. Date of Service, Physician, Room Number and abbreviated case description on all documents

Legibility of all documents is required and must include:

1. Complete product descriptions, quantities, units of measure, and contracted pricing
2. Use of one line per product
3. Complete vendor contact information for representative responsible for the case

Modifications are not to be made to the UMC Universal Vendor Packing Slip without prior approval of the Surgical Services Materials Manager. Invoicing may be completed once a Purchase Order is received from UMC Materials Management Department. Pricing must be in compliance with Exhibit A, attached, or the Universal Vendor Packing Slip will be rejected. Purchase Orders are issued as timely as possible. Notification in writing (electronic mail) can be forwarded to the Materials Management Department no sooner than ten (10) days post date of surgery. Additional contacts can be made through the Surgical Services Materials Manager.

8. Payment Terms

Payments shall be made within thirty (30) days of receipt of an approved invoice as described in Section 7 above.

9. Confidentiality

Supplier acknowledges that UMC is public county-owned hospital which is subject to the provisions of the Nevada Public Records Act, Nevada Revised Statutes Chapter 239, and as such its contracts are public documents available to copying and inspection by the public. If UMC receives a demand for the disclosure of any information related to this Agreement which Supplier has claimed to be confidential and proprietary, such as Supplier's programs, services, business practices or procedures, UMC will immediately notify Supplier of such demand and Supplier shall immediately notify UMC of its intention to seek injunctive relief in a Nevada

court for protective order. Supplier shall indemnify and defend UMC from any claims or actions, including all associated costs and attorney's fees, demanding the disclosure of Supplier document in UMC's custody and control in which Supplier claims to be confidential and proprietary.

10. Non-Excluded Healthcare Provider:

Supplier represents and warrants to UMC that neither it nor any of its affiliates (a) are excluded from participation in any federal health care program, as defined under 42 U.S.C. §1320a-7b (f), for the provision of items or services for which payment may be made under such federal health care programs and (b) has arranged or contracted (by employment or otherwise) with any employee, contractor or agent that such party or its affiliates know or should know are excluded from participation in any federal health care program, to provide items or services hereunder. Supplier represents and warrants to UMC that no final adverse action, as such term is defined under 42 U.S.C. §1320a-7e (g), has occurred or is pending or threatened against such Supplier or its affiliates or to their knowledge against any employee, contractor or agent engaged to provide items or services under this Agreement (collectively "Exclusions / Adverse Actions").

11. False Claims Act

a. The state and federal False Claims Act statutes prohibit knowingly or recklessly submitting false claims to the Government, or causing others to submit false claims. Under the False Claims Act, a supplier may face civil prosecution for knowingly presenting reimbursement claims: (1) for services or items that Supplier knows were not actually provided as claimed; (2) that are based on the use of an improper billing code which the provider knows will result in greater reimbursement than the proper code; (3) that the provider knows are false; (4) for services represented as being performed by a licensed professional when the services were actually performed by a non-licensed person; (5) for items or services furnished by individuals who have been excluded from participation in federally-funded programs; or (6) for procedures which the provider knows were not medically necessary. Violation of the civil False Claims Act may result in fines of up to $11,000 for each false claim, treble damages, and possible exclusion from federally-funded health programs. Accordingly, all employees, volunteers, medical staff members, vendors, and agency personnel are prohibited from knowingly submitting to any federally or state funded program a claim for payment or approval that includes fraudulent information, is based on fraudulent documentation or otherwise violates the provisions described in this paragraph.

b. Hospital is committed to complying with all applicable laws, including but not limited to Federal and State False Claims statutes. As part of this commitment, UMC has established and will maintain a Corporate Compliance Program, has a Corporate Compliance Officer, and operates an anonymous 24-hour, seven-day-a-week compliance Hotline. Supplier is expected to immediately report to UMC's Corporate Compliance Officer directly at (702) 383-6211, through the Hotline (888) 691-0772, or the website at http://umcsn.alertline.com, or in writing, any actions by a medical staff member, UMC supplier, or UMC employee which Supplier believes, in good faith, violates an ethical, professional or legal standard. UMC shall treat such information confidentially to the extent allowed by applicable law, and will only share such information on a bona fide need to know basis. UMC is prohibited by law from retaliating in any way against any individual who, in good faith, reports a perceived problem.

12. Budge Act and Fiscal Fund Out Clause.

In accordance with the Nevada Revised Statutes (NRS 354.626), the financial obligations under this Agreement between the parties shall not exceed those monies appropriated and approved by UMC for the then current fiscal year under the Local Government Budget Act. This Agreement shall terminate and UMC's obligations under it shall be extinguished at the end of any of UMC's fiscal years in which UMC's governing body fails to appropriate monies for the ensuing fiscal year sufficient for the payment of all amounts which could then become due under this Agreement. UMC agrees that this section shall not be utilized as a subterfuge or in a discriminatory fashion as it relates to this Agreement. In the event this section is invoked, this Agreement will expire on the 30th day of June of the current fiscal year. Termination under this section shall not relieve UMC of its obligations incurred through the 30th day of June of the fiscal year for which monies were appropriated.

13. Term of Agreement

This Agreement is effective as of _____ 1, 2011 (the "Effective Date") and expires on _____, 2013. Either party may terminate this Agreement at any time by giving thirty (30) days' advanced written notice to the other party.

14. Insurance
Supplier shall carry Commercial General Liability and Automobile Liability Insurance, in the amount of no less than $1,000,000 per occurrence, $2,000,000 aggregate during the term of Agreement and shall provide proof of coverage upon request by UMC.

15. Governing Law and Jurisdiction
This Agreement shall be construed and enforced in accordance with the laws of the State of Nevada without regard to its choice of law provisions and the jurisdiction and venue of the federal and state courts in Las Vegas, Nevada.

16. Entire Agreement.
This document, including Exhibits A and B, constitutes the entire agreement between the parties, whether written or oral, and supersedes all other agreements between the parties which provide for the same products as contained in this Agreement.

Agreed to and Accepted by:

Company Name: _____
Authorized Representative Signature: _____
Printed Name: _____
Date: _____
Attention To (for notice) _____
Address (for notice) _____
City, State, Zip _____

University Medical Center of Southern Nevada _____
Kathleen Silver, CEO _____
Date: _____
Attention To (for notice) **CEO**
Address (for notice) **1800 W. Charleston Blvd**
City, State, Zip **Las Vegas, NV 89102**

Exhibit A
Pricing Schedule

1. Cochlear Implant Products

Part	Qty	$ per Item

2. Other

Part	Qty	$ per Item

Exhibit B

UNIVERSITY MEDICAL CENTER OF SOUTHERN NEVADA
STERILE PROCESSING DEPARTMENT
POLICY AND PROCEDURES

SUBJECT: LOANED/CONSIGNED INSTRUMENT TRAYS, RECEIVING, DECONTAMINATION & VENDOR REQUIREMENTS
EFFECTIVE: 7/96 REVISED: 10/06, 2/08, 4/10
POLICY #: 107
AFFECTS: Sterile Processing/OR

I. PURPOSE:

To establish guidelines for the receiving and processing of loaned instruments/sets from vendors for scheduled or emergency surgical cases.

II. POLICY:

All loaned instruments/sets must be received by Sterile Processing at least 8 hours prior to the start time of the scheduled surgery. Emergent deliveries will be handled on a case-by-case basis through Sterile Processing and the O.R. Charge Nurse. On arrival all loaned instruments/sets will be considered contaminated whether received wrapped and sterilized from another facility or delivered unwrapped, and must undergo cleaning and sterilization on campus at UMC. Prior to arrival it is the responsibility of the manufacturer's representative to inspect instruments for damage and insure they are free of all visible bioburden.

III. PROCEDURE:

1. The sales representative will either personally deliver the instrument/sets or have them shipped directly to the UMC loading dock.
2. The UMC Consignment / Loaner form (see attached) is completed and signed by the vendor. Information on the Consignment/Loaner form includes-
   a) Vendor / Company name
   b) Date / Time of delivery
   c) Number of trays delivered
   d) Description of trays
   e) Do the instrument/sets contain implantable items?
   f) Surgical case information including Surgeon, date and time of scheduled case.
3. A copy of the manufacturers cleaning and sterilization instructions for the instrument/set will be provided by the vendor.
4. Once the instrument/set have been inventoried and inspected by the vendor representative, they then will be delivered to the decontamination area of Sterile Processing for cleaning.
5. Manufacturers instructions and Sterile Processing Policy &Procedure #'s 400 - 700 are followed for cleaning and sterilization. General guidelines include –
   a) Manually clean instruments if needed including sonic for any cannulated item/s.
   b) If tolerated place in automated washer to complete washing and decontamination cycles.
   c) At the completion of the wash cycle excess water is wiped from the tray and any cannulated items are forced air dried.
   d) The appropriate sterility assurance monitors are included and instrument/set wrapped and initialed by employee processing the item see Policy &Procedure #501, 502 & 503.
   e) A copy of the UMC Consignment / Loaner form is attached to the tray and the manufacturers recommended sterilization time noted.
6. Manufacturers sterilization guidelines and Sterile Processing Policy & Procedure's 600-700's are followed including the monitoring of all implantable item sterilization loads with Biological Indicators.
7. At the completion of the sterilization cycle, instrument/sets are allowed to cool. Once the results of the sterility assurance monitors including Biological Indicators have been read the instrument/sets can be released to the O.R. for use.
8. Once the surgical procedure is complete the soiled instruments are returned to Sterile Processing via the soiled elevator for cleaning and decontamination.
9. Once cleaned it is the expectation that all loaned instruments will be inspected and removed from the UMC campus by the vendor within 24 hours of the completion of the procedure.

Reference
AAMI Recommended Practices

INSTRUCTIONS FOR COMPLETING THE
DISCLOSURE OF OWNERSHIP/PRINCIPALS FORM

Purpose of the Form

The purpose of the Disclosure of Ownership/Principals Form is to gather ownership information pertaining to the business entity for use by the Board of County Commissioners ("BCC") in determining whether members of the BCC should exclude themselves from voting on agenda items where they have, or may be perceived as having a conflict of interest, and to determine compliance with Nevada Revised Statute 281A.430, contracts in which a public officer or employee has interest is prohibited.

General Instructions

Completion and submission of this Form is a condition of approval or renewal of a contract or lease and/or release of monetary funding between the disclosing entity and the appropriate Clark County government entity. Failure to submit the requested information may result in a refusal by the BCC to enter into an agreement/contract and/or release monetary funding to such disclosing entity.

Detailed Instructions

All sections of the Disclosure of Ownership form must be completed. If not applicable, write in N/A.

Business Entity Type – Indicate if the entity is an Individual, Partnership, Limited Liability Company, Corporation, Trust, Non-profit Organization, or Other. When selecting 'Other', provide a description of the legal entity.

Non-Profit Organization (NPO) - Any non-profit corporation, group, association, or corporation duly filed and registered as required by state law.

Business Designation Group – Indicate if the entity is a Minority Owned Business Enterprise (MBE), Women-Owned Business Enterprise (WBE), Small Business Enterprise (SBE), or Physically-Challenged Business Enterprise (PBE). This is needed in order to provide utilization statistics to the Legislative Council Bureau, and will be used only for such purpose.

Minority Owned Business Enterprise (MBE):
An independent and continuing business for profit which performs a commercially useful function and is at least 51% owned and controlled by one or more minority persons of Black American, Hispanic American, Asian-Pacific American or Native American ethnicity.

Women Owned Business Enterprise (WBE):
An independent and continuing business for profit which performs a commercially useful function and is at least 51% owned and controlled by one or more women.

Physically-Challenged Business Enterprise (PBE):
An independent and continuing business for profit which performs a commercially useful function and is at least 51% owned and controlled by one or more disabled individuals pursuant to the federal Americans with Disabilities Act.

Small Business Enterprise (SBE):
An independent and continuing business for profit which performs a commercially useful function, is not owned and controlled by individuals designated as minority, women, or physically-challenged, and where gross annual sales does not exceed $2,000,000.

Business Name (include d.b.a., if applicable) – Enter the legal name of the business entity and enter the "Doing Business As" (d.b.a.) name, if applicable.

Corporate/Business Address, Business Telephone, Business Fax, and Email – Enter the street address, telephone and fax numbers, and email of the named business entity.

Local Business Address, Local Business Telephone, Local Business Fax, and Email – If business entity is out-of-state, but operates the business from a location in Nevada, enter the Nevada street address, telephone and fax numbers, point of contact and email of the local office. Please note that the local address must be an address from which the business is operating from that location. Please do not include a P.O. Box number, unless required by the U.S. Postal Service, or a business license hanging address.

Number of Clark County Nevada Residents employed by this firm.

List of Owners/Officers – Include the full name, title and percentage of ownership of each person who has ownership or financial interest in the business entity. If the business is a publicly-traded corporation or non-profit organization, list all Corporate Officers and Directors only.

For All Contracts – **(Not required for publicly-traded corporations)**

1) Indicate if any individual members, partners, owners or principals involved in the business entity are a Clark County full-time employee(s), or appointed/elected official(s). If yes, the following paragraph applies.

   In accordance with NRS 281A.430.1, a public officer or employee shall not bid on or enter into a contract between a government agency and any private business in which he has a significant financial interest, except as provided for in subsections 2, 3, and 4.

2) Indicate if any individual members, partners, owners or principals involved in the business entity have a second degree of consanguinity or affinity relation to a Clark County full-time employee(s), or appointed/elected official(s) (reference form on Page 2 for definition). If **YES**, complete the Disclosure of Relationship Form. Clark County is comprised of the following government entities: Clark County, University Medical Center of Southern Nevada, Department of Aviation (McCarran Airport), and Clark County Water Reclamation District. Note: The Department of Aviation includes all of the General Aviation Airports (Henderson, North Las Vegas, and Jean).

A professional service is defined as a business entity that offers business/financial consulting, legal, physician, architect, engineer or other professional services.

Signature and Print Name – Requires signature of an authorized representative and the date signed.

Disclosure of Relationship Form – If any individual members, partners, owners or principals of the business entity is presently a Clark County employee, public officer or official, or has a second degree of consanguinity or affinity relationship to a Clark County employee, public officer or official, this section must be completed in its entirety.

SAMPLE

DISCLOSURE OF OWNERSHIP/PRINCIPALS

Business Entity Type						
☐ Sole Proprietorship	☐ Partnership	☐ Limited Liability Company	☐ Corporation	☐ Trust	☐ Non-Profit Organization	☐ Other

Business Designation Group					
☐ MBE	☐ WBE	☐ SBE	☐ PBE	☐	☐
Minority Business Enterprise	Women-Owned Business Enterprise	Small Business Enterprise	Physically Challenged Business Enterprise		

Corporate/Business Entity Name:			
(Include d.b.a., if applicable)			
Street Address:		**Website:**	
City, State and Zip Code:		**POC Name and Email:**	
Telephone No:		**Fax No:**	
Local Street Address:		**Website:**	
City, State and Zip Code:		**Local Fax No:**	
Local Telephone No:		**Local POC Name Email:**	
Number of Clark County Nevada Residents Employed:			

All entities, with the exception of publicly-traded and non-profit organizations**,** must list the names of individuals holding more than five percent (5%) ownership or financial interest in the business entity appearing before the Board.

Publicly-traded entities and non-profit organizations shall list all Corporate Officers and Directors in lieu of disclosing the names of individuals with ownership or financial interest. The disclosure requirement, as applied to land-use applications, extends to the applicant and the landowner(s).

Entities include all business associations organized under or governed by Title 7 of the Nevada Revised Statutes, including but not limited to private corporations, close corporations, foreign corporations, limited liability companies, partnerships, limited partnerships, and professional corporations.

Full Name	Title	% Owned (Not required for Publicly Traded Corporations/Non-profit organizations)

This section is not required for publicly-traded corporations.

1. Are any individual members, partners, owners or principals, involved in the business entity, a Clark County, University Medical Center, Department of Aviation, or Clark County Water Reclamation District full-time employee(s), or appointed/elected official(s)?

   ☐ Yes ☐ No (If yes, please note that County employee(s), or appointed/elected official(s) may not perform any work on professional service contracts, or other contracts, which are not subject to competitive bid.)

2. Do any individual members, partners, owners or principals have a spouse, registered domestic partner, child, parent, in-law or brother/sister, half-brother/half-sister, grandchild, grandparent, related to a Clark County, University Medical Center, Department of Aviation, or Clark County Water Reclamation District full-time employee(s), or appointed/elected official(s)?

   ☐ Yes ☐ No (If yes, please complete the Disclosure of Relationship form on Page 2. If no, please print N/A on Page 2.)

I certify under penalty of perjury, that all of the information provided herein is current, complete, and accurate. I also understand that the Board will not take action on land-use approvals, contract approvals, land sales, leases or exchanges without the completed disclosure form.

Signature	Print Name
Title	Date

Revised 3/1/11

DISCLOSURE OF RELATIONSHIP

List any disclosures below:
(Mark N/A, if not applicable.)

NAME OF BUSINESS OWNER/PRINCIPAL	NAME OF COUNTY* EMPLOYEE/OFFICIAL AND JOB TITLE	RELATIONSHIP TO COUNTY* EMPLOYEE/OFFICIAL	COUNTY* EMPLOYEE'S/OFFICIAL'S DEPARTMENT

* County employee means Clark County, University Medical Center, Department of Aviation, or Clark County Water Reclamation District.

"Consanguinity" is a relationship by blood. "Affinity" is a relationship by marriage.

"To the second degree of consanguinity" applies to the candidate's first and second degree of blood relatives as follows:

- Spouse – Registered Domestic Partners – Children – Parents – In-laws (first degree)
- Brothers/Sisters – Half-Brothers/Half-Sisters – Grandchildren – Grandparents – In-laws (second degree)

For County Use Only:

If any Disclosure of Relationship is noted above, please complete the following:

☐ Yes ☐ No Is the County employee(s) noted above involved in the contracting/selection process for this particular agenda item?

☐ Yes ☐ No Is the County employee(s) noted above involved in anyway with the business in performance of the contract?

Notes/Comments:

_____
Signature

_____
Print Name
Authorized Department Representative