



Monterey County

168 West Alisal Street,
1st Floor
Salinas, CA 93901
831.755.5066

Board Order

Agreement No.: A-13020

Upon motion of Supervisor Phillips, seconded by Supervisor Parker and carried by those members present, the Board of Supervisors hereby:

- a. Authorized the Deputy Purchasing Agent for Natividad Medical Center (NMC) or his designee to execute an Agreement with California Transplant Services dba SafetyGraft for Tissue Bank Services at NMC for an amount not to exceed \$175,000 for the term January 1, 2016 through December 31, 2020.
- b. Authorized the Deputy Purchasing Agent for NMC or his designee to execute up to three (3) future amendments to the agreement which do not significantly alter the scope of work and do not cause an increase of more than ten percent (10%) of the original cost of the agreement per each amendment.


PASSED AND ADOPTED on this 15th day of December 2015, by the following vote, to wit:

AYES: Supervisors Armenta, Phillips, Salinas, Parker and Potter
 NOES: None
 ABSENT: None

I, Gail T. Borkowski, Clerk of the Board of Supervisors of the County of Monterey, State of California, hereby certify that the foregoing is a true copy of an original order of said Board of Supervisors duly made and entered in the minutes thereof of Minute Book 78 for the meeting on December 15, 2015

Dated: January 7, 2016
File ID: A 15-393

Gail T. Borkowski, Clerk of the Board of Supervisors
County of Monterey, State of California

By  Deputy



Monterey County

168 West Alisal Street,
1st Floor
Salinas, CA 93901
831.755.5066

Board Report

Legistar File Number: A 15-393

December 15, 2015

Introduced: 11/19/2015

Current Status: Agenda Ready

Version: 1

Matter Type: BoS Agreement

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RECOMMENDATION:

It is recommended the Board of Supervisors:

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- b. Authorize the Deputy Purchasing Agent for NMC or his designee to execute up to three (3) future amendments to the agreement which do not significantly alter the scope of work and do not cause an increase of more than ten percent (10%) of the original cost of the agreement per each amendment.

SUMMARY/DISCUSSION:

California Transplant Services, Inc. (CTS) is licensed by the California Department of Public Health and is an IRS qualified 501(c) 3 non-profit public charity. CTS operates an eye and tissue bank offering physicians worldwide quality tissue for transplant and is accredited by the American Association of Tissue Banks and a member of the Eye Bank Association of America.

NMC would like to establish a five year agreement with California Transplant Services because of its need to appropriately store tissue such as bone flaps. NMC performs craniotomies that require patient's skull flaps to be removed. These bone flaps will be properly stored at California Transplant Services. Currently flaps are stored in a freezer located in the Surgery Department. Contracting with CTS assures proper storage and availability no matter where the patient has their skull flaps implanted.

California Transplant Services (CTS) will supply NMC with procurement packs for NMC's use

in procuring autologous tissue (skull flaps). Once the skull flap has been acquired, CTS will be contacted and the tissue sent to CTS. CTS will pay for couriers, shipment, and carriage of all autologous bone or skull flaps. CTS shall be responsible for package inspection and notifying NMC if the package is compromised and potentially not suitable for re-implantation.

OTHER AGENCY INVOLVEMENT:

County Counsel has reviewed and approved this Agreement as to legal form and risk provisions, and the Auditor-Controller has reviewed and approved as to payment provisions. The Agreement has also been reviewed and approved by NMC's Finance Committee on 10/22/15 and by its Board of Trustees on 11/6/15.

FINANCING:

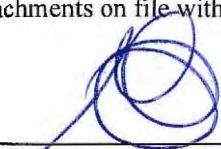
The cost for this Agreement is \$175,000 of which \$35,000 is included in the Fiscal Year 2015-16 Adopted Budget. Amounts for remaining years of the Agreement will be included in those budgets as appropriate. There is no impact to the General Fund.

Prepared by: Sue Rodgers, MSN MSHA RN, Interim Surgical Services Director, 772-7789
Approved by: Gary R. Gray, DO, Chief Executive Officer, 783-2504

Attachments:

Original Agreement with California Transplant Services dba SafetyGraft

Attachments on file with the Clerk of the Board



Gary R. Gray, Chief Executive Officer



Date

AUTOLOGOUS TISSUE STORAGE AGREEMENT
by and between
CALIFORNIA TRANSPLANT SERVICES, INC.
and
THE COUNTY OF MONTEREY on behalf of NATIVIDAD MEDICAL CENTER

"CTS":

CALIFORNIA TRANSPLANT SERVICES, INC.
dba SAFETYGRAFT
5845 Owens Avenue
Carlsbad, CA 92008

"HOSPITAL":

COUNTY OF MONTEREY ON THE BEHALF OF
NATIVIDAD MEDICAL CENTER
1441 Constitution Blvd.
Salinas, CA 93906

This Autologous Tissue Storage Agreement ("Agreement") consists of this signature page, the attached Terms and Conditions, and the Exhibits marked below. This Agreement authorizes California Transplant Services, Inc., a California nonprofit public benefit corporation, d/b/a SafetyGraft, hereinafter referred to as "CTS" to obtain from Natividad Medical Center, a Safety Net Hospital, owned and operated by Monterey County hereinafter referred to as "Hospital", human autologous tissue which CTS may process and distribute such autologous tissue for use in reimplantation. The term of this Agreement shall commence on the effective date, which is the date of execution and shall expire five (5) years thereafter unless sooner terminated by either party with or without cause by giving one hundred eighty (180) days prior written notice to the other party. For purposes of this Agreement, the effective date shall be the last date executed below. This Agreement becomes legally binding upon signature below by authorized representatives of the parties.

Exhibits

- A— Business Associate Agreement (BAA)
- B— American Association of Tissue Banks Accreditation Certificate
- C— FDA Tissue Bank Registration
- D— State of California Tissue Bank License
- E— Certificate of Liability Insurance

CALIFORNIA TRANSPLANT SERVICES, INC.

By: _____



Daryl S. Lirman, President & CEO

Date: _____

11/17/15

NATIVIDAD MEDICAL CENTER:

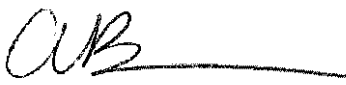
By: _____



Gary Cozy CEO

Date: _____

1/8/16



ABretun
Dep. County Counsel
11-19-15

Reviewed as to fiscal provisions



Auditor-Controller
County of Monterey

11-19-15

TERMS AND CONDITIONS

1. PROCUREMENT PROCEDURE

CTS shall provide Hospital with all procurement packs without charge for Hospital to use in procuring autologous tissue by Hospital. Hospital shall be responsible for safe and adequate storage of the autograft storage kits provided to Hospital by CTS and liable for the adequacy of all other supplies and instruments used in its procurement process. Procurement packs delivered to Hospital by CTS that are lost by Hospital, or damaged due to improper storage or careless handling by Hospital will be replaced by CTS and will incur a charge in accordance with the fee schedule in this agreement.

Hospital shall immediately notify CTS by telephone of the readiness and availability of human autologous bone or skull flaps for shipment to CTS. The Hospital shall notify CTS by calling 1(800) 928-4778 or 1(760) 804-6890. Hospital shall provide to CTS all aseptically procured autologous tissue in containers or packaging supplied to Hospital by CTS, or other suitable packaging which complies with applicable federal, state and local requirements for transportation of human autologous bone or skull flaps and/or blood specimens. Any packaging other than that supplied by CTS must be approved by CTS prior to its use by Hospital.

Hospital shall provide complete copies of the results of all bacteriological cultures and/or serological testing results (if performed by Hospital on the autologous tissue) corresponding to each shipment of autologous tissue to CTS, unless Hospital and CTS agree in advance that CTS will be performing such testing after receipt of microbiological swab specimen and qualified blood samples.

2. SHIPPING

CTS shall pay for the cost of couriers, shipment, and carriage for all donor autologous bone or skull flaps picked up by courier or shipped from Hospital to CTS's laboratory. The risk of damage or loss for all such shipments shall remain with Hospital. Hospital shall pay return processing, handling, and shipping costs on all shipments which CTS returns to Hospital. Risk of damage or loss for all such shipments shall be the responsibility of Hospital.

Hospital shall include with each shipment of autologous tissue to CTS, a fully completed and signed "Tissue Preservation Service Request Form" and shall also provide a copy of Hospital's patient "face sheet" in a format acceptable to CTS.

Any Protected Health Information (PHI) that may be contained on the Hospital's patient face sheet sent with the autologous tissue shall be considered as PHI under the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), the Health Information Technology for Economic and Clinical Health Act ("HITECH") privacy provisions of the American Recovery and Reinvestment Act, as well as to the California privacy laws which are codified in the California Health and Safety Code and in the Confidentiality of Medical Information Act (CMIA). As such, this information shall only be used by CTS in a manner consistent with patient identification and location for tracking and notification purposes, and shall at all times be kept confidential in accordance with HIPAA regulations.

Hospital shall not write or adhere on the outside of the outer cardboard box/shipping container any PHI or document that contains PHI.

For purposes of patient identification, if only a trauma name (alias) is available at the time of autologous tissue recovery and packaging is performed and are therefore provided by Hospital on the Tissue Preservation Service Request Form and Hospital Face Sheet, the true patient name, medical record number, and patient contact information shall be provided by Hospital to CTS as soon as the true patient identification information can be determined by Hospital.

Hospital shall be solely responsible for obtaining all appropriate and required informed consents necessary prior to procurement of any autologous bone or skull flap to be shipped to CTS.

CTS shall promptly inspect the outer packaging that autologous bone or skull flaps are received in from Hospital and shall promptly notify Hospital if it determines that the outer packaging of any autologous bone or skull flap or other tissue it receives from Hospital has been breached, or is in a condition that renders the autologous bone

or skull flap or other tissue compromised or not suitable for re-implantation. Any inspection of autologous bone or skull flaps or other tissue by CTS shall be of the outer packaging only and not of the bone or other tissue contained within. Therefore, nothing in CTS' inspection of the outer packaging that autologous bone or skull flaps and other tissue is received in from Hospital shall be construed in any way to be a determination by CTS of the usability, safety, suitability, determination of the presence or absence of any communicable disease, or a determination of the presence or absence of any serological or bacteriological testing of the tissue received.

3. BILLING

Hospital shall endeavor to issue a purchase order number to CTS within 30 days of date of service. CTS will invoice the Hospital's accounts payable department for each autologous bone or skull flap submitted to CTS for storage indicating on the invoice the purchase order number, patient initials, medical record number, and date of service. CTS shall submit such invoice periodically or after a billable service has been rendered or after each autologous tissue is submitted to CTS for storage, but in any event, not later than 30 days after the billable service has been rendered or an autologous tissue is submitted for storage by Hospital. Hospital shall certify the invoice for accuracy without undue delay, either in the requested amount or in such other amount as Hospital approves in conformity with this Agreement, and shall promptly submit such invoice to the County Auditor-Controller for payment. The County Auditor-Controller shall pay the amount certified within 30 days of receiving the certified invoice.

Should Hospital find it cannot certify any particular invoice, or item on an invoice for the amount stated, Hospital shall notify CTS in writing within fourteen (14) days of receipt by Hospital stating the reason for the action to not certify the invoice, and shall state the amount, if any, Hospital believes to be correct in accordance with the fee schedule in the agreement. Failure by Hospital to notify CTS of a disputed invoice within thirty (30) days shall waive Hospital's objection to the invoice as submitted to Hospital.

Hospital shall be responsible for paying any and all costs incurred by CTS in the collection of past due amounts under this agreement including collection, attorney, court and other reasonable costs as may be permissible by state law.

4. FEES

This fee schedule will continue for five years from the effective date of this Agreement. Hospital shall pay CTS for its participation in the Autograft Storage Program in accordance with the following fee schedule:

Hospital Autologous bone or skull flap storage fees for participating hospitals:

| SERVICES | CHARGE | DESCRIPTION |
|--------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Autologous storage: kit and service. | <p>\$2,995.00 per kit inclusive, effective for years 1, and 2 of this agreement.</p> <p>\$3,200.00 per kit inclusive, effective for years 3 and 4 of this agreement.</p> <p>\$3,300.00 for year 5 of this agreement.</p> <p>\$1,065.00 per kit inclusive, for each additional one year continued storage term, or part thereof beyond the initial two year term inclusive during the term of this agreement.</p> | <p>Note: If autologous kits are provided to Hospital, but then subsequently stored and used at another facility other than Hospital, CTS shall be entitled to charge for autologous tissue storage services for the kit(s) as if used by Hospital.</p> <p>Continued storage beyond two years may incur an additional storage fee to be billed and payable annually at the beginning of the additional storage term.</p> <p>CTS shall notify Hospital of autologous tissue 3 to 6 months prior to expiration of the initial two (2) year storage term to allow Hospital time to determine the need for additional storage, or decision</p> |

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|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | to allow disposal of the tissue. If an additional storage term is desired by Hospital, CTS shall invoice Hospital upon the commencement of the additional storage term. If Hospital determines an additional storage term(s) is not wanted, Hospital shall provide CTS with its authorization to cease continued storage and to dispose of the tissue without further liability and in accordance with regulatory requirements. |
| Standard return shipping to Hospital. | <p>\$200.00 per kit inclusive, years 1, 2, and 3 of this agreement.</p> <p>\$250.00 per kit inclusive, years 4 and 5 of this agreement.</p> | <p>Requests for return orders received by CTS during normal business hours, 7 am to 5 pm M-F PST for next day surgical times after 7 a.m.</p> <p>Requests made after 5 pm M-F for next day deliveries, or for Sat., Sun., and public holiday deliveries shall be considered outside of normal business hours and shall incur a STAT Shipping Fee. Arrival of tissue at Hospital. Delivery shall be during evening hours for 7:00 am cases, otherwise during normal business hours.</p> |
| STAT Shipping Fee for same day return to hospital, or delivery to Hospital on Saturday, Sunday, and public holidays. | <p>\$300.00 per kit inclusive, years 1, 2, and 3 of this agreement.</p> <p>\$375.00 per kit inclusive, years 4 and 5 of this agreement.</p> | STAT charge is made in place of regular shipping charge; courier or normal commercial shipping methods. |
| Improperly packaged tissue, or shipments packaged by Hospital that do not comply with CTS' packaging instructions and result in a shipment being refused or otherwise not accepted by common carrier shipper. | There shall be incurred by Hospital an additional stat shipping fee to cover the round trip courier and handling fees required, together with a charge for an additional replacement autologous storage kit, as is necessary to properly tender the tissue. Charges shall be billed according to the then current fee in effect for the service during the year of this agreement. CTS shall provide Hospital with a statement as to why any additional charges are charged due to improperly packaged tissue, together with photograph(s) as is practical to do so. | The fee charged is for special handling and cost of couriers (which may be considerable), together with the fee for a replacement autologous storage kit as necessary when the tissue is rejected by an airline or common carrier due to improper packaging (usually leaking water caused by improper placement and sealing of zip lock ice pouches by Hospital staff) by the Hospital requiring the tissue to be returned to the facility for repackaging by the Hospital's OR staff prior to being retendered to the common carrier for transport. |

| | | |
|---------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Replacement of lost or damaged autologous storage kits. | <p>\$250.00 inclusive, years 1, 2, and 3 of this agreement.</p> <p>\$300.00 inclusive, years 4 and 4 of this agreement.</p> | Each kit is numbered and assigned to Hospital. Kits are initially placed at no charge based on projected usage and number of kits assigned may be adjusted according to utilization. Missing, damaged and lost kits shall incur a replacement fee. |
| Disposal of autologous tissue. | <p>\$50.00 inclusive, years 1, 2 and 3 of this agreement.</p> <p>\$75.00 inclusive, years 4 and 5 of this agreement.</p> | Fee charged for disposal and documentation of autologous tissue as regulated Medical Waste (RMW). |

5. RIGHT TO REFUSE

CTS reserves the exclusive right to refuse acceptance of any autologous tissue, or other tissue it is sent by Hospital, its physicians or staff without obligation or liability. CTS may exercise this right to refuse acceptance for several reasons, including but not limited to:

1. Failure by Hospital, its physicians and staff to timely and adequately notify CTS that an autologous bone or skull flap or other autograft tissue has been recovered and is ready for pick-up by CTS.
2. Failures by Hospital, its physicians and staff to timely make the autograft tissue accessible and available to CTS' staff or authorized representatives at the hospital for pick-up and retrieval for shipment to CTS.
3. Failure by Hospital, its physicians and staff to utilize the Autograft Preservation Kit and its contents. Deviation from using these materials must be done in a manner that is safe and suitable, and will not cause the possibility of personnel exposure to any communicable disease. Deviations from normal packaging materials and/or procedures must be done in conjunction with timely notice to CTS of a deviation and the nature of the deviation.
4. Failure by Hospital to fully complete the autograft preservation order form or to obtain the surgeon's or other authorized signature at the bottom of the form.
5. Failure by Hospital, its physicians and staff to follow CTS' instructions as provided and/or updated as to the correct packaging and shipment of autologous bone or skull flaps or other autograft tissue.
6. Improper and/or unsafe packaging of autologous bone or skull flaps or other autograft tissue by Hospital, its physicians and staff. Improper or unauthorized use of solutions, media, or other materials in the preparation or packaging of the autograft tissue. Infection of the tissue with a biological agent that would render it unsafe or dangerous despite using normally accepted procedures for handling donor tissue and Universal Precautions as published by the CDC.
7. Failure by Hospital to include the prescribed quantity of solidly frozen wet ice, or other suitable cold packs to the box containing the tissue for shipment to CTS, or in an adequate quantity, prior to making the shipping container available for pick-up by CTS or its authorized representative.

6. EXCLUSIVITY

CTS shall have the exclusive right to store autologous tissue for the Hospital. Hospital shall not use any other agency, firm or source for autologous bone or skull flap storage, during the term of this agreement. Should CTS become unable to accept additional autologous storage submissions due to regulatory action, natural disaster, or other unforeseeable circumstance Hospital shall have the right to submit and store autologous tissue with another agency or firm until such time as CTS is again able to receive submissions of autologous tissue.

7. ACCREDITATION/LICENSURE/FEDERAL REGISTRATION

CTS hereby represents and warrants that it is fully accredited by the American Association of Tissue Banks (AATB) and that it will maintain such accreditation throughout the term of this Agreement. CTS will comply with all standards of procedure and operation required by the AATB and all applicable federal regulations, including, without limitation, those found under 21 CFR 1271, and state laws and regulations throughout the term of this Agreement. CTS will maintain licensure by the California Department of Health Services as a Human Tissue Preservation Laboratory throughout the term of this agreement, and shall be registered from year to year with the United States Food and Drug Administration for the storage and distribution of human bone.

8. COMPLIANCE WITH STANDARDS

Hospital hereby represents and warrants to CTS that Hospital will comply with all regulations, standards of procedure, and operations required by the Joint Commission on Accreditation of Healthcare Organizations with oversight over Hospital, whether or not Hospital is accredited by the Joint Commission. Hospital will also comply will all applicable local, state, and federal laws and regulations throughout the term of this Agreement.

9. INSTRUCTION MODIFICATION

If Hospital modifies any documents that CTS has previously approved for Hospital's use in the autologous tissue procurement process, CTS must first approve all such modifications prior to their use by Hospital. CTS shall also have the right to require Hospital to use updated CTS forms as they are provided to Hospital or otherwise made available by CTS.

10. STATUS OF PATIENT

Hospital, its physicians, and agents shall notify timely CTS of the death of any patient that has provided a autologous tissue to CTS and that still has the autologous tissue banked with CTS' autograft storage program. Hospital shall notify CTS of any change of contact information it knows of for the treating physician for any patients that has autologous tissue on deposit with CTS. CTS shall periodically send patient status forms to the patient's treating physician to be completed by the treating physician regarding the disposal or continued storage of the autologous bone or skull flap being banked for the patient by CTS. Hospital, its physicians and agents shall timely and accurately complete the patient status forms and return them to CTS thereby instructing CTS on the continued storage or destruction of the autologous tissue stored. Failure to return these patient status forms accurately completed within sixty (60) days of receipt shall be considered a material breach of this Agreement.

If after two (2) years from the date of autologous tissue procurement and shipment of the autologous tissue to CTS for storage in the autograft storage program, CTS can no longer contact the patient, identify the patient's legal guardian, and cannot reasonably ascertain the patient's treating physician or a medical professional legally authorized to advocate on behalf of the patient CTS shall send a certified letter with return receipt to the address where the patient was last known to reside stating this fact and the intention of CTS to dispose of the autologous bone or skull flap being stored. CTS shall dispose of the autologous bone or skull flap as biomedical waste under the following conditions:

- 1) Thirty (30) days has passed after the receipt of the notice by the patient/the patient's legal guardian to make contact with CTS regarding continuing autograft tissue storage arrangements; or
- 2) Thirty (30) days has passed after return of the letter as undeliverable by the US Postal Service and CTS has made reasonable attempts to locate the patient.

11. COMMENTS OR COMPLAINT NOTIFICATION

CTS and Hospital shall immediately notify the other party upon receipt of any adverse serological or bacteriological test results and/or any adverse reactions, or deviations from procedure either during the procurement or resulting from any use of human autograft tissue under this Agreement that becomes known to either party. In the event of an adverse reaction, Hospital will immediately notify CTS for determination of suitability of FDA or American Association of Tissue Banks adverse reaction notification.

12. BOOKS AND RECORDS

Hospital and CTS shall each maintain complete records on all of their sterilization, cleaning, procurement, testing, processing, distribution, and disposition procedures. Such records shall be made available during

normal business hours for the other party's inspection upon not less than seven days prior written notice. Each party shall be responsible for its own expenses in conducting such inspection and/or audits. CTS shall have the right to inspect Hospital's physical facilities, procedures, and records relevant to the recovery of autologous bone and skull flaps. Such inspection shall be performed during regular business hours upon fourteen (14) days prior written notice. Hospital shall in good faith consider reasonable changes requested by CTS in any of the Hospital's relevant procedures related to the recovery, handling, shipping, and record keeping of autologous bone and skull flaps after an audit or inspection by CTS.

13. CONFIDENTIAL INFORMATION

Hospital shall not use in any way other than as required for the proper performance of its obligations under this Agreement and shall not provide to or disclose to any party any of the information given to it by CTS or otherwise acquired by the Hospital relating to CTS' products, processes, plans, records, documentation, forms, techniques, procedures, donor information, test results, customers, trade secrets or general business operations. Any information legally in Hospital's possession prior to disclosure to it by a CTS representative, which is lawfully published or which otherwise lawfully becomes a part of general knowledge from sources other than CTS, shall not be subject to the restrictions of this Section 13.

14. TERM and TERMINATION

This agreement shall be effective as of the latter date after being executed by both parties ("Effective Date") and shall continue for a period of 5 (five) years. The following provisions shall govern the right, duties and obligations of the parties upon termination of this Agreement however occurring:

- a. Termination shall not release or affect, and this Agreement shall remain fully operative, as to any obligations or liabilities incurred by either party prior to the effective date of such termination; provided that all indebtedness of either party of any kind shall become immediately due and payable on the effective date of termination. Hospital may deduct from any sums it owes to CTS any sums owed by CTS to Hospital.
- b. Termination of this Agreement shall not terminate any provision of this Agreement intended to survive termination, including but not limited to Section 13, 15, 23 and 24.
- c. Either party may terminate this agreement with or without cause by providing the other party written notification by US Mail ninety (90) days prior to the date of termination.

15. DAMAGES

It is agreed by and between the parties that CTS is providing autograft tissue storage services as outlined in this agreement to Hospital, its patients, staff, and physicians as a community service. It is understood by all parties concerned that the services under this agreement are being rendered by CTS as, and by a non-profit corporation. Furthermore, it is agreed between the parties that CTS is in no way, and it shall not be construed under this agreement that CTS is in any way in control, in supervision, or direction of patient care, the surgical surroundings, surgical procedures, general medical arts or care that is rendered by Hospital, its staff and physicians to its patients, or the outcome of any surgical procedure performed that is related to this agreement. It is agreed by Hospital and CTS that CTS shall not be responsible for the procurement, packaging, shipment, processing of tissue if any, storage, return shipment, re-implant of tissue into the patient, or the success or failure of any procedure performed on or on behalf of the patient under this agreement or that is provided by CTS. Furthermore, it is agreed by Hospital and CTS that at no time shall it be construed by and between the parties that CTS is providing anything but a service, and that nothing under this agreement shall be deemed the sale or dispensing of a product, or any act or activity that is subject to the uniform commercial code. CTS makes no other express or implied warranties of any kind, including express or implied warranties of merchantability, as to the success or failure of the procurement, shipment, processing if any, storage, handling, return shipment, re-implantation, or as to any other handling or use of the autograft tissue that it is sent by Hospital, its physicians or staff. In no event shall CTS be liable for any direct, indirect, incidental, consequential, special, or other damages including, but not limited to any legal or court costs, attorney fees, or other forms of damages that would be reasonably contemplated by this agreement.

Notwithstanding terms, conditions or provisions to the contrary, any limitation(s) of liability, indemnity or remedies set forth herein do not apply in the event that the service(s) and/or product(s) provided by CTS result in injury or death to persons, or damage to real or personal property.

16. INDEPENDENT CONTRACTOR STATUS

Hospital and CTS shall act at all times under this Agreement as independent contractors, and neither party shall have any right or authority, express or implied to create or to assume any obligation on behalf of the other party hereto.

No relationship of employer and employee is created by this Agreement, it understood that CTS and its employees and subcontractors will act hereunder as independent contractors, not being subject to the direction and control of Hospital in their day to day provision of contract services. CTS shall not assign, sell, or otherwise transfer its interest or obligations in this Agreement without the prior written consent of Hospital. Furthermore, CTS shall not have any claim under this Agreement or otherwise against Hospital for vacation pay, sick leave, retirement benefits, social security contribution, workers' compensation, disability or unemployment insurance benefits, or any other employee benefit of any kind.

17. LIMITATION ON ACTION

No action arising out of any transaction under this Agreement, regardless of cause or form, may be brought by either party under this Agreement against the other party more than two (2) years after the date the aggrieved party becomes reasonably aware of the event leading to the cause of action first accrues, but in no event after three (3) years after the date of the transaction

18. FORCE MAJEURE

Performance under this Agreement, or any part thereof, may be excused or delayed, and neither party shall be held in breach of any of its obligations under this Agreement or be liable for damages or offset resulting from such delay if such delay is due to causes beyond the reasonable control of the party such as, but not limited to, acts of God, acts of civil or military authority, terrorism, fires, floods, failure of electrical services or other public utilities, labor troubles, cancellation, delay, or unavailability of transportation, epidemics, war or riot.

19. TRANSPORTATION DELAY AND LOSS OF TISSUE

The parties to this agreement acknowledge and agree that transportation of autograft tissue shall be transported from Hospital to CTS by way of CTS employees, common carrier commercial transportation, airlines, couriers, shipping companies, and other subcontracted entities outside the direct control of Hospital or CTS. It is also agreed that unforeseen circumstances may cause undue delay or prevent the successful transport, preservation, storage, return shipment, or re-implantation of the autograft tissue by the employees and agents of Hospital and CTS. Therefore, it is understood and agreed that Hospital and CTS shall be excused from all obligation, liability, damages, economic loss, bodily harm, or even loss of life for any damage to the autograft or its loss, or for any circumstance or event that may render the autograft unusable or unsuitable for acceptance by CTS, processing, storage, return shipment, or for surgical re-implantation by Hospital that is caused by handling during transport, damage to external or internal packaging, damage caused by unforeseen delay in transit, loss, mysterious disappearance, exposure to toxic or noxious chemicals, freezing, thawing, excessive heat, heat wave, or due any other event or circumstance that may cause the autograft tissue from being successfully re-implanted into the patient, other than such event or circumstance caused by the gross negligence of CTS and its employees.

The parties to this agreement acknowledge and agree that the storage of autograft tissue shall be done with all due care and recognition of the importance of all such tissue sent for storage and re-implantation. However, the parties recognize that circumstances may arise that are unforeseeable, or that cannot be prevented despite the application of reasonable resources and care. Therefore, it is understood and agreed that Hospital and CTS shall be excused from all obligation, liability, damages, economic loss, bodily harm, or even loss of life for any damage to the autograft or its loss, or for any circumstance or event that may render the autograft unusable or unsuitable for acceptance by CTS, processing, storage, return shipment, or surgical re-implantation by Hospital that is caused by the sudden mechanical breakdown of refrigerators, freezers, or other equipment that may be used in the handling, preservation, or storage of the tissue, or for the sudden unforeseen loss of public utilities, electrical service, roving blackouts, brownouts, or failure, malfunction, or loss of backup electricity systems or liquid CO2 backup systems for freezers and other equipment.

20. DESTRUCTION

As part of this agreement Hospital, its physicians and staff shall empower and permit, without objection or injunction, CTS to destroy and dispose of any autograft tissue sent to it by Hospital for storage provided CTS has first obtained from Hospital or the patient's treating physician, the patient, or the patient's legally authorized representative a signed request for destruction and disposal, or a signed authorization for the destruction and disposal of the tissue. CTS shall only destroy or dispose of any tissue sent to it by Hospital and that has been accepted by CTS for storage, by safe and legal means, and such destruction and disposal shall be performed in compliance with all applicable regulatory requirements for the County of San Diego and state of California. Hospital, its physicians and staff shall not unreasonably withhold authorization for the destruction and disposal of any autograft tissue stored by CTS. If CTS is unable to obtain a signed authorization for the destruction and disposal of any tissue sent to it by Hospital, its physicians and staff CTS shall have the right to charge Hospital for the continued storage of such tissue until such time that CTS has determined that it can legally destroy and dispose of the tissue.

21. RETURN OF TISSUE

CTS shall promptly return autograft tissue after it has received verbal telephonic instructions from an authorized representative of Hospital and a valid purchase order number for the return handling and shipping fees relating to the tissue stored. CTS shall have the right to have any order for the return of autograft tissue to Hospital concurrently followed-up with the order in writing via mail or fax to CTS' offices. All orders for return of autograft tissue shall be made with reasonable advance notice sufficient to allow CTS to safely transport the tissue to Hospital or other designated location without extraordinary means or jeopardizing the safety of personnel or the autograft. Generally, notice for the return of tissue shall be given to CTS by Hospital as soon as possible, but not later than 24 hours in advance prior to the time the tissue must arrive at the receiving location prior to the scheduled surgery. It is agreed by Hospital that tissue requested for return shall be sent for specific scheduled surgery dates, and shall not be ordered returned greater than 24 hours prior to the scheduled dates of re-implant of the tissue or for the continued day to day storage at Hospital.

CTS shall return autograft tissue pursuant to receiving proper legal demand from authorized parties (legal next of kin) and/or government agencies (Medical Examiner or County Coroner) to appropriate and suitable locations, and Hospital agrees that it shall be responsible for paying any return shipment and handling fees that CTS normally charges in addition to any extraordinary costs that CTS must incur as part of compliance with such orders unless other arrangements for payment have been made by the entity requesting or ordering the return.

22. PUBLICATION

No announcement, news release, public statement, publication or presentation relating to the existence of this Agreement, the subject matter herein, or either party's performance hereunder will be made without the other party's prior written approval, except as required by law. Neither party will, without the prior written consent of the other party, which shall not unreasonably be withheld: (a) use in advertising, publicity, promotional premiums or otherwise, any trade name, trademark, trade device, service mark, symbol, or other abbreviation, contraction or simulation thereof owned by the other party; or represent, either directly or indirectly, that any product or service of the other party is a product or service of the representing party.

Notwithstanding the foregoing, CTS understands and acknowledges that Hospital is subject to the California Public Records Act and the Ralph M. Brown Act.

23. PROFESSIONAL LIABILITY INSURANCE

Hospital shall obtain and maintain in force during the term of this Agreement, and for the extended period of its provisions, hospital liability insurance coverage (or adequate self-insurance to cover its liability under this agreement and equivalent in coverage and terms to a customary and usual hospital liability insurance policy with minimum limits as described herein), under a policy or policies issued by a carrier satisfactory to CTS, with minimum limits of \$1,000,000 basic coverage plus \$1,000,000 excess liability coverage on any such policy issued on a claim made basis and with minimum limits of \$1,000,000 basic coverage with \$4,000,000 excess liability coverage on any such policy issued on an occurrence basis with, in all cases, no more than a \$50,000 deductible on any such policy. Maintenance of or failure to maintain such insurance or self-insurance shall not relieve Hospital of any liability under this Agreement.

Prior to commencement of this Agreement, the CTS shall provide a "Certificate of Insurance" certifying that coverage as required herein has been obtained.

CTS shall obtain and maintain in force during the term of this Agreement products, completed operations and professional liability insurance coverage under a policy or policies issued by a carrier satisfactory to Hospital, with minimum limits of \$2,000,000 per occurrence and \$4,000,000 aggregate issued on a claims made basis with no more than a \$50,000 deductible on any such policy. Maintenance of such insurance shall not relieve CTS of any liability under this Agreement.

CTS shall also obtain and maintain in force during the term of this Agreement Workers' Compensation Insurance, If CTS employs others in the performance of this Agreement, in accordance with California Labor Code section 3700 and with Employer's Liability limits not less than \$1,000,000 each person, \$1,000,000 each accident and \$1,000,000 each disease.

CTS shall obtain and maintain in force during the term of this Agreement Business automobile liability insurance, covering all motor vehicles, including owned, leased, non-owned, and hired vehicles, used in providing services under this Agreement, with a combined single limit for Bodily Injury and Property Damage of not less than \$1,000,000 per occurrence.

24. INDEMNITY

To the extent allowable under law, each party agrees to indemnify and hold harmless the other, and the other's respective officers, directors, agents, contractors, representatives and employees and each of their affiliates from and against any and all liability, loss, and damages, and expenses associated therewith (including without limitation reasonable attorneys' fees and costs) where such liability, loss and damages have been finally adjudicated by a court of competent jurisdiction and only to the extent such liability, loss and damages were caused by or resulted from the negligent acts, errors or omissions of the indemnifying party, its contractors, shareholders, employees, or agents. This indemnity clause shall not be applicable to any liability, loss, and damages caused by the actions, failure, or negligence of third party government agencies, or common carriers such as professional courier services and airlines.

25. GOVERNING LAW

This Agreement shall be construed and enforced in accordance with the laws of the State of California without regard to its choice of law provisions.

26. NOTIFICATION OF LEGAL CLAIMS

In the event Hospital or CTS has received knowledge of a legal claim in regard to any services provided by CTS or Hospital under this Agreement, or has been served with or has knowledge of a lawsuit filed in regard to any services provided by CTS or Hospital under this Agreement the party in possession of the knowledge or that has been served with a lawsuit shall promptly within fourteen (14) calendar days notify the other party and shall provide a copy of the complaint to be sent by certified mail return receipt if so served. Failure to comply with this provision shall be deemed by the parties to be a material breach of this Agreement.

27. HEALTHCARE REGULATORY

a. Use of Outside Resources. Pursuant to Title 22 of the Licensing and Certification of Health Facilities and Referral Agencies of the State of California in respect to Section 70713 Use of Outside Resources, the parties agree that Hospital retains professional and administrative responsibility for the services rendered and will comply with all other requirements of Section 70713.

b. Fraud & Abuse & OIG Compliance With Medicare/Medicaid Exclusion Rules. It is acknowledged that the Hospital's Compliance Program applies to the services and obligations described herein. This program is intended to prevent compliance concerns such as fraud, abuse, false claims, excess private benefit and inappropriate referrals. This compliance program requires and it is hereby agreed that any regulatory compliance concerns shall be promptly reported either to an appropriate manager or through the hotline (800-850-2551). CTS represents and warrants that it and its employees or agents are not and at no time have been debarred or excluded from participation in any federally funded health care

program, including Medicare and/or Medicaid. CTS hereby agrees to immediately notify Hospital of any threatened, proposed or actual exclusion of itself, an employee or agent from any federally funded health care program, including Medicare and/or Medicaid. Failure to abide by these compliance requirements shall immediately and automatically terminate this Agreement.

c. No Physician Ownership. CTS hereby represents and warrants to Hospital that no physician, no physician organization and/or no member of a physician's immediate family (1) owns or holds an ownership in CTS; (2) has a financial interest in CTS or (3) has any type of financial relationship with CTS.

d. Conflict of Interest Disclosure. CTS represents and warrants that neither CTS nor any affiliate of CTS nor any officers, directors, employees, partners, members, owners or shareholders of CTS or any affiliate of CTS is related to, affiliated in any way with, or employs (or otherwise has a compensation interest with) any officer, director or employee of Hospital.

e. Licenses. CTS will provide Hospital with copies of all applicable state and federal licenses and certifications required to lawfully conduct its business in California. It is a condition precedent to performance by either party hereunder that all such CTS licenses and certifications are valid and current. CTS agrees that it will ensure, verify, and confirm that all employees or agents performing under its control have the proper licenses, trainings, qualifications, and competencies required to perform the job for which they have been hired.

f. Compliance With Laws. In the performance of the duties required under this Agreement, both parties shall comply with all applicable laws, ordinances, and codes of local, state and federal governments, including but not limited to the Health Insurance portability and Accountability Act (HIPAA), Health Information Technology for Economic and Clinical Health Act (HITECH), California Confidentiality of Medical information Act (COMIA), California Information Practices Act (IPA), California privacy laws detailed in the California Health and Safety Code as a result of AB 211 and SB 541 regarding misuse of patient information, as well as The Joint Commission standards.

g. Jeopardy. If the performance by a Party hereto of any term, covenant, condition or provision of this Agreement (i) jeopardizes the licensure of any facility owned, operated or managed by Hospital or any of its affiliates (collectively "Facility"), (ii) jeopardizes participation in Medicare, Medi-Cal or other reimbursement or payment programs, (iii) jeopardizes the full accreditation of any facility by the Joint Commission on Accreditation of Healthcare Organizations or any other state or nationally recognized accreditation organization, (iv) jeopardizes the tax-exempt status of Hospital or any financing of Hospital or (v) violates any statute or ordinance, or is otherwise deemed to have acted illegally, or is deemed unethical by any recognized body, agency, or association in the medical or hospital fields (collectively, a "Jeopardy Event"), then the parties shall meet forthwith and shall use their best efforts to negotiate an amendment to this Agreement to remove or negate the effect of the Jeopardy Event. If the parties are unable to negotiate such an amendment within five (5) business days following written notice by Hospital of the Jeopardy Event, then Hospital may terminate this Agreement immediately, followed by written Notice of Suspension.

h. Books and Records. In accordance with state and federal law, CTS and Hospital agree that until the expiration of five (5) years after the furnishing of services provided under this Agreement, CTS will retain and make available to the State of California, the Secretary of the United States Department of Health and Human Services (the "Secretary") and the United States Comptroller General, and their duly authorized representatives, this Agreement and all books, documents and records necessary to verify the nature and costs of those services, provided that access is required by cited law and regulations, and further provided that the request for such access complies with the procedural requirements of these regulations.

If CTS carries out any of the duties of this Agreement through a subcontract with a value or cost of \$10,000 or more over a twelve (12) month period with a related organization, the subcontract will also contain an access clause to permit access by the Secretary, the United States Comptroller General and their representatives to the related organization's books and records. This paragraph shall not, however,

be construed to permit services to be rendered thereunder by any person or entity other than CTS, without the approval of Hospital. Further, no attorney-client or other legal privilege will be deemed to have been waived by Hospital or CTS by virtue of this Agreement.

i. Responsibility for Contract. In the event that subcontracting is permitted and utilized by CTS under this Agreement, CTS retains the prime responsibility for carrying out all the terms of this Agreement, including the responsibility for performance in accordance with the terms of the Agreement and insuring the availability and retention of records of subcontractors in accordance with this Agreement. The preceding does not create a right to subcontract nor does it grant the CTS permission to subcontract work not otherwise expressly permitted to be subcontracted under the terms of the Agreement.

j. Right to Audit and Confirm Compliance. Upon reasonable written notice to CTS, Hospital may inspect relevant portions of CTS's records to verify CTS's compliance with this Agreement. Any failure by Hospital to inspect such records will not be construed as a waiver of any of Hospital's rights and remedies set forth herein.

k. Severability. If any provision of this Agreement is held to be invalid, illegal, unenforceable or otherwise inoperative, the remainder of this Agreement shall remain in full force and effect as if said provision were not included in this Agreement.

26. MISCELLANEOUS

- a. This Agreement contains the entire agreement between the parties and supersedes any and all other oral or prior written agreements or understandings. This Agreement may not be amended except by a written document signed by both parties.
- b. All notices required or desired to be given under this Agreement shall be deemed delivered when deposited in U.S. Certified Mail, return receipt requested, postage prepaid, addressed to the recipient at the address indicated in the signature page of this Agreement or at such other address as the recipient may hereafter provide to the other party hereto.

Notice to CTS:


California Transplant Services, Inc.
dba SafetyGraft
Daryl Lirman, President and CEO
5845 Owens Avenue
Carlsbad, CA 92013-0815

Notice to Hospital:

County of Monterey on the behalf of
Natividad Medical Center
Legal Services Department
1441 Constitution Blvd.
Salinas, CA 93906


- c. The services provided herein are exempt from HIPPA authorization requirements under HHS Regulations: Uses and Disclosures for Organ, Eye or Tissue Donation Purposes - § 164.512(h). However, CTS acknowledges that in the performance of services under this agreement it shall be considered a Business Associate of Hospital, and defined in HIPAA, and as such agrees to be bound by the terms of the Business Associate Agreement (BAA) attached as Exhibit A.
- d. It is the objective of CTS and the SafetyGraft autologous tissue storage service to run smoothly, without incident or error, and for the benefit of Hospital and patient. Toward achieving this goal, CTS makes available periodic in-service training for Hospital's surgical staff. Hospital shall make available appropriate operating room staff for periodic in-service training at times convenient to both Hospital and CTS. There shall be no additional charge to Hospital or staff for this in-service training.
- e. This Agreement may not be assigned by either Party without the prior written consent of the other Party, which shall not be unreasonably withheld. Notwithstanding any provision of this Agreement to the contrary, either Party shall have the right to assign or otherwise transfer its interest under this Agreement, without consent of the other Party, to any successor in connection with the merger, reorganization, consolidation, or sale of all or substantially all of its assets or that portion of its business pertaining to the subject matter of this Agreement.

For Hospital:

By: 
County of Monterey on the behalf of Natividad Medical Center

Date: 11/8/16

For CTS:

By: 
Daryl Liman, President and CEO
California Transplant Services, Inc.

Date: 11/17/15

END OF TERMS AND CONDITIONS




A Breerton

Dep. County Counsel

11-19-15

Reviewed as to fiscal provisions


Auditor-Controller
County of Monterey

11-19-15

BUSINESS ASSOCIATE AGREEMENT

This Business Associate Agreement ("Agreement") is entered between the **County of Monterey on behalf of Natividad Medical Center** ("Covered Entity") and **California Transplant Services, Inc. d/b/a SAFETYGRAFT** ("Business Associate").

Background

Pursuant to the parties' separate autologous tissue storage agreement ("Services Agreement"), Business Associate has agreed to perform certain services for or on behalf of Covered Entity that may involve the creation, maintenance, use, transmission or disclosure of protected health information within the meaning of the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), and its implementing regulations, 45 CFR Parts 160 and 164 ("HIPAA Rules"). This Agreement supplements the Services Agreement and all other concurrent and future agreements between the parties that may involve protected health information and compliance with HIPAA. The Agreement is intended to and shall be interpreted to satisfy the requirements for business associate agreements as set forth in the HIPAA Rules as they have been amended, including but not limited to privacy and security amendments of the Affordable Care Act and the HHS Omnibus Final Rule. Business Associate understands and acknowledges that Business Associate is subject to the HIPAA Rules, and that the violation of the HIPAA Rules carry significant penalties as described in 45 CFR § 160.404. Business Associate also understands that Business Associate is subject to and must comply with the Health Information Technology for Economic and Clinical Health Act ("HITECH") privacy provisions of the American Recovery and Reinvestment Act, as well as to the California privacy laws which are codified in the California Health and Safety Code and in the Confidentiality of Medical Information Act (CMIA) ("California Privacy Laws"). The parties agree as follows:

Definitions

1. **General Definitions.** The following terms used in this Agreement shall have the same meaning as those terms in the HIPAA Rules: *Breach, Data Aggregation, Designated Record Set, Disclosure, Health Care Operations, Individual, Minimum Necessary, Notice of Privacy Practices, Required By Law, Secretary, Security Incident, Subcontractor, Unsecured Protected Health Information, and Use.*

2. **Specific Definitions.**

a. **Business Associate** shall generally have the same meaning as the term "business associate" at 45 CFR § 160.103, and in reference to the party to this Agreement, shall mean Business Associate.

b. **Covered Entity** shall generally have the same meaning as the term "covered entity" at 45 CFR § 160.103, and in reference to the party to this Agreement, shall mean Covered Entity.

c. **Protected Health Information** shall generally have the same meaning as the term "protected health information" at 45 CFR § 160.103, and shall include any individually identifiable information that is created, received, maintained, or transmitted by Business Associate on behalf of Covered Entity that relates to an individual's past, present, or future physical or mental health, health care, or payment for health care, whether such information is in oral, hard copy, electronic, or any other form or medium.

Agreement

1. **Relationship of the Parties.** Business Associate is and at all times during this Agreement shall be acting as an independent contractor to Covered Entity, and not as Covered Entity's agent. Covered Entity shall not have authority to control the method or manner in which Business Associate performs its services on behalf of Covered Entity, provided that Business Associate complies with the terms of this Agreement and the HIPAA Rules. Business

Associate shall not have authority to bind Covered Entity to any liability unless expressly authorized by Covered Entity in writing, and Covered Entity shall not be liable for the acts or omissions of Business Associate. Business Associate shall not represent itself as the agent of Covered Entity. Nothing in this Agreement shall be deemed to establish an agency, partnership, joint venture or other relationship except that of independently contracting entities.

2. Business Associate Responsibilities. Business Associate agrees to:

- a.** Fully comply with the HIPAA Rules as they apply to business associates.
- b.** Not use or disclose protected health information except as permitted by this Agreement or as otherwise required by law.
- c.** Use appropriate safeguards to prevent the use or disclosure of protected health information other than as permitted by this Agreement. Business Associate shall comply with the requirements in 45 CFR Part 164, Subpart C applicable to business associates, including the use of administrative, physical and technical safeguards to protect electronic protected health information.
- d.** Immediately upon discovery report to Covered Entity any use or disclosure of protected health information not permitted by this Agreement, the California Privacy Laws or the HIPAA Rules of which Business Associate becomes aware, including but not limited to reporting breaches of unsecured protected health information as required by 45 CFR § 164.410, reporting security incidents as required by 45 CFR § 164.314(a)(2)(i)(C) and reporting breaches and security incidents of Business Associate's contractors and subcontractors.
- e.** Fully cooperate with Covered Entity's efforts to promptly investigate, mitigate, and notify third parties of breaches of unsecured protected health information or security incidents as required by the HIPAA Rules.
- f.** Ensure that any subcontractors that create, receive, maintain, or transmit protected health information on behalf of Business Associate agree to the same restrictions, conditions, and requirements set forth in this Agreement, the California Privacy Laws and the HIPAA Rules applicable to such subcontractors. Business Associate may fulfill this requirement by executing a written agreement with the subcontractor incorporating the terms of this Agreement and otherwise complying with the requirements in 45 CFR §§ 164.502(e)(1)(i)(ii)-(2) and 164.308(b)(1)-(3).
- g.** Within ten (10) days following Covered Entity's request, make available to Covered Entity any protected health information in Business Associate's control as necessary to enable Covered Entity to satisfy its obligations to provide an individual with access to certain protected health information under 45 CFR § 164.524.
- h.** Within ten (10) days following Covered Entity's request, make available to Covered Entity any protected health information for amendment and incorporate any amendments to protected health information as necessary to enable Covered Entity to satisfy its obligations under 45 CFR § 164.526.
- i.** Maintain information concerning Business Associate's or subcontractors' disclosures of protected health information as required by 45 CFR § 164.528(a)-(b) and, within ten (10) days following Covered Entity's request, make such information available to Covered Entity as necessary to enable Covered Entity to render an accounting of disclosures pursuant to 45 CFR § 164.528.
- j.** To the extent Business Associate is to carry out Covered Entity's obligations under 45 CFR Part 164, Subpart E, comply with the requirements of Subpart E that apply to Covered Entity in the performance of such obligations.
- k.** Make Business Associate's internal practices, books, and records relating to the use and disclosure of protected health information received from, or created or received by Business Associate on behalf of Covered Entity, available to the Secretary for purposes of determining Covered Entity's compliance with the HIPAA Rules.

1. For as long as the Business Associate shall be in possession of any Protected Health Information in any form, the Business Associate shall periodically test, monitor and audit their information security systems, measures and procedures in order to ensure that such systems, measures and procedures are consistent with industry best practices and standards. If any audit or review reveals any material security defects, problems, weaknesses, or vulnerabilities, Business Associate shall correct the defect, problem, weakness or vulnerability immediately, and if this is not possible, the Business Associate shall notify the Chief Legal Officer of the Covered Entity immediately. Covered Entity also reserves the right to audit Business Associate to ensure compliance with privacy and security laws and regulations.

3. Uses and Disclosures by Business Associate.

3.1 **Permissible Uses and Disclosures.** Business Associate may use or disclose protected health information only as follows:

- a. As necessary to perform the services set forth in the Service Agreement.
- b. To de-identify protected health information in accordance with 45 CFR § 164.514(a)-(c).
- c. As required by law.
- d. For the proper management and administration of Business Associate or to carry out the legal responsibilities of Business Associate, provided that any disclosures for these purposes (i) are required by law, or (ii)(a) Business Associate obtains reasonable assurances from the person to whom the information is disclosed that the information will remain confidential and used or further disclosed only as required by law or for the purposes for which it was disclosed to the person, and (ii)(b) the person notifies Business Associate of any instances of which it is aware in which the confidentiality of the information has been breached.
- e. To provide data aggregation services relating to the health care operations of Covered Entity as defined in 45 CFR § 164.501.

3.2 **Impermissible Uses or Disclosures.** Business Associate may not use or disclose protected health information in a manner that would violate 45 CFR Part 164, Subpart E, if done by Covered Entity except for the specific uses and disclosures set forth in Sections 3.1(a)-(e), if applicable.

3.3 **Minimum Necessary.** Business Associate agrees to use or disclose the minimum amount of protected health information necessary for a permitted purpose pursuant to this Section 3, Covered Entity's policies and procedures, and 45 CFR § 164.502(b).

4. **Term and Termination.** Unless otherwise agreed in writing by the parties, this Agreement shall be effective as of the date executed by the parties and shall continue until terminated as provided below.

4.1 **Termination.** This Agreement shall terminate on the date the Services Agreement is terminated for any reason. In addition, this Agreement may be terminated earlier as follows:

Covered Entity may terminate this Agreement upon thirty (30) days prior notice if Covered Entity determines that Business Associate or any subcontractor has violated the HIPAA Rules, or a material term of this Agreement. Business Associate shall have the opportunity to cure the breach or violation within the 30-day notice period. If Business Associate fails to cure the breach or violation within the 30-day notice period, Covered Entity may declare this Agreement terminated.

4.2 **Termination of Services Agreement.** Notwithstanding anything in the Services Agreement to the contrary, Covered Entity shall have the right to terminate the Services Agreement immediately if Business Associate's creation, maintenance, use, transmission or disclosure of protected health information is a material purpose of the Service Agreement and this Agreement is terminated for any reason.

4.3 Obligations of Business Associate Upon Termination. Upon termination of this Agreement for any reason, Business Associate shall, with respect to protected health information received from Covered Entity, or created, maintained, used, or received by Business Associate on behalf of Covered Entity:

a. If feasible, return all protected health information to Covered Entity or, if Covered Entity agrees, destroy such protected health information. The return of all protected health information shall be accompanied by a certification signed by an officer of Business Associate, certifying that the returned information is all of Covered Entity's protected health information in all formats and media and that no protected health information remains in Business Associate's possession. If Covered Entity agrees to allow Business Associate to destroy such protected health information, Business Associate shall provide Covered Entity with a certification of destruction signed by an officer of Business Associate, certifying that all of Covered Entity's protected health information in all formats and media has been destroyed and that no protected health information remains in Business Associate's possession.

b. If the return or destruction of protected health information is not feasible, continue to extend the protections of this Agreement and the HIPAA Rules to such information and not use or further disclose the information in a manner that is not permitted by this Agreement or the HIPAA Rules and Business Associate will notify the Chief Legal Officer of the Covered Entity in writing. Said notification shall include: (i) a statement that the Business Associate has determined that it is infeasible to return or destroy the Protected Health Information in its possession; and (ii) the specific reasons for such determination. Business Associate further agrees to extend any and all protections, limitations and restrictions contained in this Agreement to the Business Associate's use and/or disclosure of any Protected Health Information retained after the termination of this Agreement, and to limit any further uses and/or disclosures to the purposes that make the return or destruction of the Protected Health Information infeasible. If it is infeasible for the Business Associate to obtain from employees, contractors, subcontractors or agents any Protected Health Information in the possession of the employees, contractors, subcontractors or agents, the Business Associate must provide a written explanation to the Chief Legal Officer of Covered Entity and require the employees, contractors, subcontractors or agents to agree to extend any and all protections, limitations and restrictions contained in this Agreement to the employees', contractors', subcontractors' or agents' use and/or disclosure of any Protected Health Information retained after the termination of the Agreement, and to limit any further uses and/or disclosures to the purposes that make the return or destruction of the Protected Health Information infeasible.

4.4 Survival. Business Associate's obligations under Section 4 shall survive termination of this Agreement.

5. Regulatory References. A reference in this Agreement to a section in the HIPAA Rules means the section as in effect or as amended.

6. Amendment. The parties agree to take such action as is necessary to amend this Agreement from time to time to comply with the requirements of the HIPAA Rules and any other applicable law.

7. Governing Law. This Agreement shall be construed to comply with the requirements of the HIPAA Rules, and any ambiguity in this Agreement shall be interpreted to permit compliance with the HIPAA Rules. All other aspects of this Agreement shall be governed under the laws of the State in which Covered Entity maintains its principal place of business.

8. Assignment/Subcontracting. This Agreement shall inure to the benefit of and be binding upon the parties and their respective legal representatives, successors and assigns. Business Associate may assign or subcontract rights or obligations under this Agreement to subcontractors or third parties without the express written consent of Covered Entity provided that Business Associate complies with Section 2(f), above. Covered Entity may assign its rights and obligations under this Agreement to any successor or affiliated entity.

9. Cooperation. The parties agree to cooperate with each other's efforts to comply with the requirements of the HIPAA Rules and other applicable laws; to assist each other in responding to and mitigating the effects of any breach of protected health information in violation of the HIPAA Rules or this Agreement; and to assist the other party in responding to any investigation, complaint, or action by any government agency or third party relating to the performance of this Agreement. In addition to any other cooperation reasonably requested by Covered Entity,

Business Associate shall make its officers, members, employees, and agents available without charge for interview or testimony.

10. Notice. All notices required to be given under this Agreement must be given in writing and shall be deemed to have been sufficiently given if personally delivered or deposited in the United States mail, postage prepaid, certified or registered mail, return-receipt requested, addressed as follows:

**If to Covered Entity,
Natividad Medical Center:**

County of Monterey, on behalf of Natividad Medical Center
Attn: Legal Services Department
1441 Constitution Blvd.
Salinas, CA 93906

**If to Business Associate,
California Transplant Services, Inc., d/b/a SAFETYGRAFT:**

California Transplant Services, Inc., dba: SAFETYGRAFT
Attn: President and CEO (Daryl Lirman)
5845 Owens Avenue
Carlsbad, CA 92008

11. Relation to Services Agreement. This Agreement supplements the Services Agreement. The terms and conditions of the Services Agreement shall continue to apply to the extent not inconsistent with this Agreement. If there is a conflict between this Agreement and the Services Agreement, this Agreement shall control.

12. No Third Party Beneficiaries. Nothing in this Agreement is intended to nor shall it confer any rights on any other persons except Covered Entity and Business Associate and their respective successors and assigns.

13. Entire Agreement. This Agreement contains the entire agreement between the parties as it relates to the use or disclosure of protected health information, and supersedes all prior discussions, negotiations and services relating to the same to the extent such other prior communications are inconsistent with this Agreement.

14. Insurance. Unless waived in writing by Covered Entity, Business Associate shall obtain and maintain insurance or equivalent programs of self-insurance with appropriate limits sufficient to cover costs, losses and damages that may arise from Business Associate's breach of this Agreement or any unauthorized use or disclosure of protected health information by Business Associate. Upon Covered Entity's request, Business Associate shall provide proof of such insurance to Covered Entity.

15. Indemnification. Business Associate agrees to defend, indemnify, and hold harmless Covered Entity and Covered Entity's officers, members, employees and agents from and against any and all claims, fines, penalties, liabilities, demands, damages, losses, costs, expenses (including without limitation costs, reasonable attorneys' fees, fines, penalties, and assessments) that are caused by or result from Business Associate's breach of this Agreement or any acts or omissions of Business Associate or Business Associate's officers, members, employees, agents, or subcontractors arising out of the use and disclosure of protected health information or violation of the HIPAA Rules.

To the extent permitted by law, Covered Entity agrees to defend, indemnify, and hold harmless Business Associate from and against any and all claims, fines, penalties, liabilities, demands, damages, losses, costs, expenses that are caused by or result from Covered Entity's breach of this Agreement or any acts or omissions of Covered Entity or Covered Entity's officers, members, employees, agents, or subcontractors arising out of the use and disclosure of protected health information or violation of the HIPAA Rules.

16. Offshore Data Storage. In furtherance of protecting the Protected Health Information received from Covered Entity, or created, maintained, used, or received by Business Associate on behalf of Covered Entity, offshore storage and use of such Protected Health Information requires prior written consent from Covered Entity.

17. **Disaster Recovery Plan.** Business Associate represents and warrants that Business Associate has a HIPAA compliant disaster recovery plan in place at, or prior to, the time of this Agreement's execution.

18. **Access to Business Associate's Security Policies and Procedures.** Covered Entity shall have access to Business Associate's security policies and procedures, and Business Associate shall cooperate with a request by Covered Entity for copies of such policies and procedures.

COUNTY OF MONTEREY, ON BEHALF OF NATIVIDAD MEDICAL CENTER
COVERED ENTITY

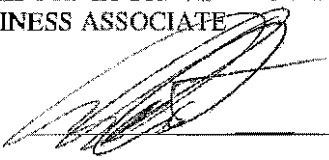
By:  _____

Print: Gary R Coey

Title: CEO

Date: 1/8/16

CALIFORNIA TRANSPLANT SERVICES, INC. d/b/a SAFETYGRAFT,
BUSINESS ASSOCIATE

By:  _____

Print: Daryl Lirman

Title: President and CEO

Date: 11/17/15

END

American Association of Tissue Banks

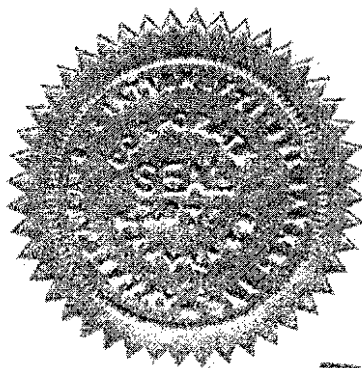
*Herewith certifies
that the Institution named here*

California Transplant Services, Inc. Carlsbad, California

*has met the Association's accreditation requirements and is hereby
accredited for Storage and Distribution of Skin and Musculoskeletal
Tissue for Transplantation as a Tissue Distribution Intermediary*

May 24, 2013 – December 19, 2015

*In witness Whereof the undersigned officers, being duly authorized, have caused this Certificate
to be issued and the Corporate Seal of this Association to be affixed hereon this the
24th day of May 2013*



Donald McLaughlin

President

J. P. Sullivan

Chief Executive Officer

Accreditation #00133/4

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
**ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS, TISSUES,
AND CELLULAR AND TISSUE-BASED PRODUCTS (HCT/Ps)**
(See reverse side for instructions)

1. REGISTRATION NUMBER
(FDA Establishment Identifier)
FEI: 3001503330

2

ADDITIONAL INFORMATION:

Proprietary Name(s):

a. Bone Autologous Bone, Donor Bone, SpinalGraft MDII,
Precision Graft

DEPARTMENT OF PUBLIC HEALTH

850 Marina Bay Parkway, Bldg P, 1st Floor
Richmond, CA 94804-6403
(510) 620-3800



Dear Tissue Bank:
Attached below is your tissue bank license.
Your license is void after the expiration date.

NOTE: Application for renewal of license must be filed with the department not less than 30 days prior to its expiration date and shall be accompanied by the annual renewal fee. (CA H&S Code §1639.2)

FORFEITURE OF LICENSE

A Tissue Bank license shall be forfeited by operation of law prior to its expiration date when one of the following occurs:

- (1) The tissue bank is sold or otherwise transferred.
- (2) The license is surrendered to the state department.

CALIFORNIA TRANSPLANT SERVICES, INC.
5845 OWENS AVE
CARLSBAD, CA 92008

ATTN: DARYL S. LIRMAN

QUESTIONS AND INFORMATION:

If you have any questions, please write to:

STATE OF CALIFORNIA
DEPT. OF PUBLIC HEALTH
Laboratory Field Services
850 Marina Bay Parkway, Bldg P, 1st Floor
Richmond, CA 94804-6403

Thank you for your cooperation.

Tear Here

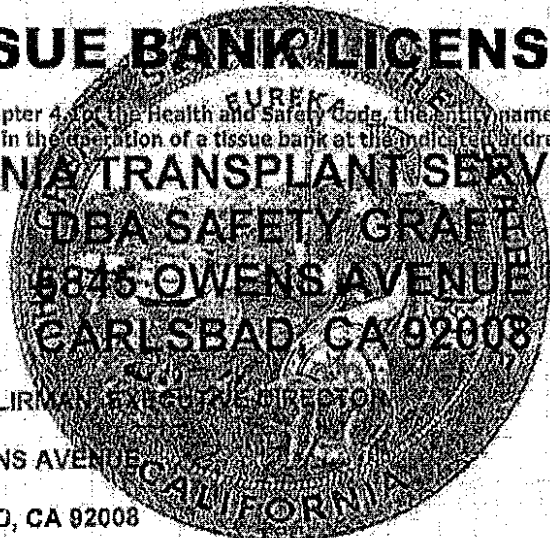
Tear Here

**STATE OF CALIFORNIA DEPARTMENT OF PUBLIC HEALTH
TISSUE BANK LICENSE**

In accordance with Division 2, Chapter 4, of the Health and Safety Code, the entity named below is hereby licensed to engage in the operation of a tissue bank at the indicated address:

CALIFORNIA TRANSPLANT SERVICES, INC.

**DBA SAFETY GRAFT
5845 OWENS AVENUE
CARLSBAD, CA 92008**



Owner(s) Name: **DARYL S. LIRMAN, EXECUTIVE DIRECTOR**
Address: **5845 OWENS AVENUE**
City, State, Zip: **CARLSBAD, CA 92008**

Tissue Bank Director:
DARYL S. LIRMAN

TISSUE BANK ID NUMBER: **CNC 80141**
Issuance Date: **OCTOBER 4, 2015**
Expiration Date: **OCTOBER 3, 2016**

Ronald Harkey
Ronald Harkey, Chief, Tissue Bank Licensing Section
Laboratory Field Services

ATTACHMENT I *California Transplant*

CLINICAL CONTRACT MANAGEMENT – REVIEW CHECKLIST

Name: Sue Rodgers Signature: Sue Rodgers
 Print

Date Completed: 11/29/16

Optional

| | | | |
|----|------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------|-----------|
| 1. | The contract requires adherence to TJC standards, CMS CoPs, state and federal law and regulation, applicable facility policies and procedures. | <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO | Comments: |
| 2. | Direct Observation of Care has been assigned to a member of the organization: Title: <u>Director</u> | <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A | Comments: |
| 4. | Establish a process to ensure Incident Reports for Contracted Services are coded for identification throughout the term of the contract | <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A | Comments: |
| 5. | Define all Routine reports required within the scope of services: 1. 2. 3. | <input type="checkbox"/> YES <input type="checkbox"/> NO <input checked="" type="checkbox"/> N/A | Comments: |



U.S. Food and Drug Administration



Department of Health and Human Services

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HUMAN CELL AND TISSUE ESTABLISHMENT REGISTRATION - Public Query
Establishment Details

Establishment Name and Location

Current Status: Registered
 Last Annual Registration Year: 2016
 FDA Establishment Identifier (FEI): 3001503330
 Establishment Name: California Transplant Services, Inc. dba SafetyGraft
 Address: 5845 Owens Avenue
 City: Carlsbad
 State: California
 Zip: 92008
 Country: United States
 Phone: 760-804-6890 ext. 101

Establishment Functions

| | Types of HCT/P's | Recover | Screen | Test | Package | Process | Store | Label | Distribute |
|----|---------------------------------|---------|--------|------|---------|---------|-------------------------------------|-------------------------------------|-------------------------------------|
| a. | Bone | | | | | | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> |
| b. | Cartilage | | | | | | <input checked="" type="checkbox"/> | | <input checked="" type="checkbox"/> |
| c. | Cornea | | | | | | <input checked="" type="checkbox"/> | | <input checked="" type="checkbox"/> |
| d. | Dura Mater | | | | | | | | |
| e. | Embryo | | | | | | | | |
| f. | Fascia | | | | | | <input checked="" type="checkbox"/> | | <input checked="" type="checkbox"/> |
| g. | Heart Valve | | | | | | | | |
| h. | Ligament | | | | | | <input checked="" type="checkbox"/> | | <input checked="" type="checkbox"/> |
| i. | Oocyte | | | | | | | | |
| j. | Pericardium | | | | | | | | |
| k. | Peripheral Blood Stem Cells | | | | | | | | |
| l. | Sclera | | | | | | <input checked="" type="checkbox"/> | | <input checked="" type="checkbox"/> |
| m. | Semen | | | | | | | | |
| n. | Skin | | | | | | <input checked="" type="checkbox"/> | | <input checked="" type="checkbox"/> |
| o. | Somatic Cell Therapy Products | | | | | | | | |
| p. | Tendon | | | | | | <input checked="" type="checkbox"/> | | <input checked="" type="checkbox"/> |
| q. | Umbilical Cord Blood Stem Cells | | | | | | | | |
| r. | Vascular Graft | | | | | | | | |
| s. | Parathyroid | | | | | | <input checked="" type="checkbox"/> | | <input checked="" type="checkbox"/> |

Establishment HCT/P Listing

| Types of HCT/P's | Proprietary Names |
|------------------|-------------------|
| | |

| | | HCT/P's Described in 21 CFR 1271.10 | HCT/P's Regulated as Medical Devices | HCT/P's Regulated as Drugs or Biological Drugs | |
|----|------------------------------------|----------------------------------------------|-----------------------------------------------|---------------------------------------------------------------|------------------------------|
| a. | Bone | X | | | Autologous Bone |
| b. | Cartilage | X | | | |
| c. | Cornea | X | | | |
| d. | Dura Mater | | | | |
| e. | Embryo | | | | |
| f. | Fascia | X | | | |
| g. | Heart Valve | | | | |
| h. | Ligament | X | | | |
| i. | Oocyte | | | | |
| j. | Pericardium | | | | |
| k. | Peripheral Blood Stem Cells | | | | |
| l. | Sclera | X | | | |
| m. | Semen | | | | |
| n. | Skin | X | | | Donor and Autologous Skin |
| o. | Somatic Cell Therapy Products | | | | |
| p. | Tendon | X | | | |
| q. | Umbilical Cord Blood Stem Cells | | | | |
| r. | Vascular Graft | | | | |
| s. | Parathyroid | X | | | Autologous Parathyroid |

HCT/P Listing - Donor Information

| | Types of HCT/P's | SIP | Directed | Anonymous | Autologous | Family Related | Allogenic |
|----|---------------------------------|-----|----------|-----------|------------|----------------|-----------|
| e. | Embryo | | | | | | |
| i. | Oocyte | | | | | | |
| k. | Peripheral Blood Stem Cells | | | | | | |
| m. | Semen | | | | | | |
| o. | Somatic Cell Therapy Products | | | | | | |
| q. | Umbilical Cord Blood Stem Cells | | | | | | |

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