



## Monterey County Board of Supervisors

### Board Order

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

[www.co.monterey.ca.us](http://www.co.monterey.ca.us)

A motion was made by Supervisor Mary L. Adams, seconded by Supervisor Chris Lopez to:

#### Agreement No.: A-16333

- a. Authorize the Chief Executive Officer for Natividad Medical Center (NMC) or his designee to execute a retroactive agreement with California Transplant Services dba SafetyGraft for tissue bank storage services at NMC, effective January 1, 2023 through December 31, 2025, not to exceed \$200,000; and,
- b. Approve the NMC Chief Executive Officer's recommendation to accept non-standard risk provisions (insurance, indemnification, limitations on liability, damages, actions) in the Agreement.

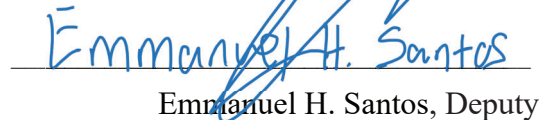
PASSED AND ADOPTED on this 6<sup>th</sup> day of June 2023, by roll call vote:

AYES: Supervisors Alejo, Church, Lopez, Askew, and Adams  
NOES: None  
ABSENT: None

I, Valerie Ralph, 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 82 for the meeting June 6, 2023.

Dated: June 7, 2023  
File ID: A 23-200  
Agenda Item No.: 18

Valerie Ralph, Clerk of the Board of Supervisors  
County of Monterey, State of California

  
Emmanuel H. Santos, Deputy

# 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— American Association of Tissue Banks Accreditation Certificate
- ☒ B— FDA Tissue Bank Registration
- ☒ C— State of California Tissue Bank License
- ☒ D— Certificate of Liability Insurance

**CALIFORNIA TRANSPLANT SERVICES, INC.**

By: \_\_\_\_\_

Daryl S. Lirman, President & CEO

Date: 04/14/2023

DocuSigned by:  
*Stacy Saelta*  
C0ECE1B99F444A9...

**NATIVIDAD MEDICAL CENTER:**

DocuSigned by:  
*Charles Harris*  
4E1F837D204E481...

CEO

Date: 6/13/2023 | 9:44 AM PDT

DocuSigned by:  
*Jennifer Forsyth*  
4E7E657875454AE...

5/9/2023 | 4:04 PM PDT

5/9/2023 | 7:46 AM PDT

## 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.

Contractor shall submit invoices periodically or at the completion of services, but in any event, not later than 30 days after completion of services and receipt of a valid purchase order from Hospital. The invoice shall set forth the amount(s) claimed by Contractor, together with an itemized basis for the amounts claimed and such other information that may be necessary pertinent to the invoice. NMC shall certify the invoice, either in the requested amount or in such other amount as NMC 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.

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. This Agreement shall not exceed \$200,000. 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.	\$4275.00	The autologous bone or skull flap storage fee for original shipment from Hospital shall provide for continuously monitored frozen storage of the autologous bone or skull flap for a period of two (2) years. If kits are used and self-stored or stored at another facility CTS is entitled to charge for the services.
	\$1075.00 for each additional one year continued storage term, or part thereof beyond the initial two-year term.	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.
Transfer to or from another hospitals inventory.	\$ TBD Quoted at the time of service	7day / 24 hour

Standard return shipping to Hospital.	\$350.00	Return orders received during normal business hours, 7am to 5 pm PST M-F, and at least 24 hrs in advance with arrival of tissue 10:30 am to 5:00 pm. Deviations may incur additional shipment expense.
STAT Shipping Fee for same day return to hospital or requiring air freight, courier, or Fed/Ex First Overnight service.	\$500.00	STAT charge is made in place of regular shipping charge; 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 an airline or 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.	The fee charged is for special handling and 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 of out outside designated pouches or improper sealing of 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 airline or common carrier for transport.
Disposal of autologous tissue.	\$100.00	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 with 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. 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  
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).
- 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.

For Hospital:

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

Date: \_\_\_\_\_

For CTS:

By: \_\_\_\_\_  
Daryl Lirman, President and CEO  
California Transplant Services, Inc.

Date: 04/14/2023  
END OF TERMS AND CONDITIONS