

AFFILIATION AGREEMENT

THIS AGREEMENT is made by and between Donor Network West, a federally designated not-for-profit Organ Procurement Organization (OPO) and tissue and eye recovery agency, and the County of Humboldt, by and through the Inpatient Psychiatric Health Facility operated by the Humboldt County Department of Health and Human Services – Behavioral Health, a political subdivision of the State of California, hereafter "Hospital."

WHEREAS, the parties are mutually dedicated to the increased availability of tissue, and eyes for transplantation and research; and

WHEREAS, the parties desire to create a collaborative model for the donation process within the hospital based on industry recognized tissue donation best practices.

WHEREAS, the parties desire to set forth the responsibilities of each with respect to the procurement of donated organs and tissues.

NOW, THEREFORE, the parties agree as follows:

ARTICLE I

Definitions

For purposes of this Agreement, the following terms shall have the meanings ascribed to them in this Article I.

0.1. Applicable Laws and Standards. Applicable Laws and Standards include:

- 0.1.1. Federal, state, and local laws, rules and regulations in effect now or at any time hereafter during the term of this Agreement that govern the process of referral, authorization, acquisition, recovery, preservation, transport and transplantation of organs, tissue and eyes including, but not limited to, the California Revised Uniform Anatomical Gift Act ("CA- RUAGA"), and rules adopted by the Centers for Medicare and Medicaid Services ("CMS"), pertaining to the performance of the duties described in this agreement, as applicable.
- 0.1.2. Accrediting Standards of the American Association of Tissue Banks (AATB) and the Eye Bank Association of America, as applicable.
- 0.2. Document of Gift. A donor card or other record, as described in California Health & Safety Code §7150.10(6), used to make an anatomical gift. The term includes a statement or symbol on a driver's license, identification card, donor California Organ and Tissue Donor Registry and advance directive.
- 0.3. Coroner/Medical Examiner (C/ME) Release or Denial: The C/ME may permit the recovery of tissues for transplantation or may deny the recovery of a tissue or tissues for transplant. A denial can only be made by the C/ME while the C/ME is attending the donor operative procedure pursuant to CA-RUAGA §7151.20.
- 0.4. Timely Notification/Referral: Hospital shall notify Donor Network West within one hour of death of the patient.
- 0.5. Tissue. The term "tissue" refers to bone, skin, corneas, eyes, heart valves, saphenous veins, or any other human tissue that may be used for human transplantation, therapy, education or research.

Main Office

12667 Alcosta Blvd., Ste. 500
San Ramon, CA 94583

Fresno Office

6721 N. Willow Ave., Ste. 104
Fresno, CA 93710

Nevada Office

1495 Ridgeview Dr., Ste. 90
Reno, NV 89519

Clinical Center

4550 Norris Canyon Rd., Ste. 100
San Ramon, CA 94583

Main Line

888.570.9400

Donor Referral Hotline

1.800.55DONOR

Tax ID 94-3062436



ARTICLE II

OPO Responsibilities

Donor Network West shall have the following responsibilities:

2.1. Referral and Response.

Donor Network West shall provide to the Hospital a one phone call referral system whereby the Hospital will be able to call Donor Network West when a hospital death occurs or is imminent. Donor Network West system shall be available on a twenty-four hour a day, seven day a week basis. Donor Network West shall provide timely communication and response to hospital by a qualified Donor Network West staff person on a twenty-four hour a day, seven day a week basis.

2.2. Evaluation

Donor Network West will obtain information from Hospital medical and nursing staff regarding the patient's medical condition and Donor Network West staff will obtain medical and social history from the appropriate individuals with knowledge of the donor.

2.2.1. Maintenance of treatment during evaluation period. Donor Network West may conduct any reasonable examination necessary to ensure the medical suitability of a part that is or could be the subject of an anatomical gift from a donor or a prospective donor. During the examination period appropriate donor maintenance shall be performed.

2.2.2. Laboratory Testing. Donor Network West shall be responsible for obtaining the appropriate laboratory testing of donors as required by applicable federal and state laws and regulations. All costs of testing shall be the responsibility of Donor Network West.

2.2.3. Diagnostic Testing. Donor Network West may conduct any reasonable test or examination necessary to evaluate the medical suitability of the body or part for its intended purpose. Donor Network West shall be responsible for ordering the appropriate diagnostic and screening tests. Biopsies. All costs of testing shall be the responsibility of Donor Network West.

2.3. Donor Authorization and Documentation.

Donor Network West will collaborate with Hospital as part of a single health care team caring for the family; Donor Network West, acting as the tissue recovery agency, and Hospital will ensure all families of potential donors within Hospital are sensitively informed about the prospective donor's decision to donate as documented by valid document of gift, or the family's option to donate, as applicable.

2.3.1. First Person Authorization for Donation. Donor Network West shall search the California Organ and Tissue Donor Registry and any other relevant donor registry to ascertain whether the individual has made an anatomical gift. If the prospective donor has a document of gift, and is medically suitable, Donor Network West and Hospital shall follow the wishes of the prospective donor as expressed. Donor Network West, in collaboration with Hospital staff, will attempt to contact the appropriate person, which may be a family member, to notify him or her of the donor's gift. In cases where family members or other appropriate persons are unavailable within a time frame compatible with donation, donation shall proceed if medically appropriate.

2.3.2. Document of Gift Irrevocable. Pursuant to CA-RUAGA § 7150.35 a person other than the donor is barred from making, amending, or revoking an anatomical gift of a donor's body or part if the donor made an anatomical gift.

2.3.3. Honor Document of Gift. Hospital shall acknowledge and support a patient's right to make an anatomical gift and shall take appropriate actions together with Donor Network West to affect the

donation when a prospective donor has executed a document of gift. Hospital will collaborate with Donor Network West to notify the donor's family members as appropriate and address any questions or concerns they may have regarding patient's legal authorization to donate, but in no circumstance shall the hospital/OPO permit a third-party to effectively revoke a gift in violation of law.

2.3.4. Third Party Authorization for Donation. In those instances where the prospective donor has not documented a gift, Donor Network West shall coordinate an appropriately timed request for donation with those who are legally entitled to donate. In cases where no person named in CA-RUAGA §7150.40 (a)(1)-(9) is reasonably available, the Hospital's administrator or any other person having the authority to dispose of the body as in §7150.40 (a)(10) may authorize donation. Donor Network West shall demonstrate sensitivity in discussions with families, including respect for family wishes.

2.3.5. Designated Requestor. Donor Network West shall be solely responsible for making the request for tissue donation from family members and/or person(s) authorized to donate on behalf of a prospective donor.

2.3.6. Documentation for Authorization. Donor Network West shall be responsible for documenting authorization for donation pursuant to CA-RUAGA §7150.20. Such authorization may be in writing, telegraphic, recorded telephonic or other recorded message. A copy of the authorization form shall become a part of the patient's medical record.

2.3.7. Confidentiality and Disclosure: The results of tests and examinations conducted by Donor Network West shall be used or disclosed only for purposes of evaluating medical suitability for donation and to facilitate the donation process, and as required or permitted by existing law.

2.3.8. Measures Necessary: Appropriate donor maintenance shall be performed for medically suitable authorized donors.

2.4. Donor Surgical Recovery.

Donor Network West shall be responsible for coordinating surgical procedures and personnel for tissue and/or eye recovery, including the coordination and provision of an appropriately qualified recovery team.

2.4.1. Coordination. Donor Network West, in collaboration with the Hospital, shall be responsible for arranging the recovery room time and the arrival/departure logistics for the recovery team.

2.4.2. Tissue and Eye Recovery. Donor Network West will coordinate surgical recovery, utilizing trained recovery technicians.

2.4.3. Transfer of Prospective Donor. If, for any reason, Hospital does not have an operating room available and one cannot be provided in an adequate time frame for the preservation of the tissue, as determined by Donor Network West, Donor Network West may transfer the prospective donor to another facility for recovery of the tissue(s) at Donor Network West's expense.

Qualified Personnel, Donor Network West staff. Donor Network West will send only qualified individuals to perform donor assessment, evaluation, authorization, and assistance with surgical retrieval of donated tissues

2.5. Coroner/Medical Examiner (C/ME) Notification and Documentation.

If the prospective donor is determined to be a coroner's case, Donor Network West will ensure that the coroner or medical examiner is notified of the death and all pertinent information pursuant to any existing protocol. C/ME release for recovery or operating room denial of recovery will be documented in the medical record.

2.6. Donor Family Communication Post-Donation. Donor Network West will provide follow-up communication with the donor family.

- 2.7. Training of Hospital Personnel. Donor Network West agrees to assist in the training of Hospital personnel who are involved in all aspects of the donation process. Donor Network West shall conduct periodic education programs for professional and administrative personnel at Hospital including:
- a. Referral and maintenance of prospective organ and/or tissue donors;
 - b. Consent process;
 - c. Role of Donor Network West staff as the designated requestor;
 - d. Importance of using discretion and sensitivity when approaching families;
 - e. Transplantation and donation, including pediatrics, if appropriate;
 - f. Quality improvement activities;
 - g. Role of hospital staff in donation process;
 - h. Role of the tissue recovery agency in the donation process.
- 2.8. Quality Assurance. Donor Network West agrees to assist Hospital in compliance with applicable standards and with the development and updating of a protocol for identifying prospective tissue donors from among patients who die in the Hospital in accordance with applicable laws and standards.
- 2.8.1. Hospital Death Record Review. Consistent with applicable laws and standards, Donor Network West may review Hospital's death records, pursuant to section 3.9 herein, for the purpose of facilitating tissue donation and transplantation including, but not limited to, furthering the Hospital's quality assurance programs.
- 2.8.2. Written Reports. Donor Network West may provide Hospital with periodic and annual written reports with hospital specific donation data and outcomes pertaining to tissue donor referral and donation activity.
- 2.8.3. Statistical Summaries. Donor Network West may provide Hospital with regular statistical summaries of Hospital-specific notification call activity to support verification of Hospital compliance with legal, accreditation and regulatory requirements pertaining to donation.
- 2.9. Cooperation with Hospital. Donor Network West shall record promptly and maintain all information pertaining to its performance of duties and services under this Agreement and Donor Network West's records relating to services performed hereunder shall be available to Hospital upon request, subject to applicable laws and regulations. Donor Network West agrees to cooperate fully with Hospital in the performance by Hospital of Hospital's responsibilities under this Agreement and federal and state laws.

ARTICLE III

Hospital Responsibilities

Hospital shall have the following responsibilities:

- 3.1. Establishment of Donor Program. Hospital agrees to cooperate fully with Donor Network West to establish a donor program to aid in the referral and recovery of potential tissue donors.
- 3.1.1. Donor Network West Designated Tissue and Eye Recovery Agency. Hospital hereby designates Donor Network West as its sole tissue and eye recovery agency. Changes to this designation may be made only upon one-hundred eighty (180) days written notice to Donor Network West.
- 3.1.2. Hospital Policies and Protocols. Hospital and Donor Network West shall cooperate in developing and approving policies and procedures to maximize donation and to further implement the provisions of this Agreement and applicable standards, and for compliance with all applicable laws, regulations, and standards relating to the donation of anatomical gift(s).
- 3.1.3. Hospital Staff Liaison. Hospital shall identify one or more staff members to serve as a donation liaison to Donor Network West.

- 3.1.4. Hospital Staff Education. Hospital shall work cooperatively with Donor Network West to facilitate continuing education to Hospital staff on all aspects of organ, tissue, and eye donation.
- 3.2. Donor Identification and Notification Procedure. Hospital shall establish a procedure for timely referral of all deaths for organ, tissue, and eye donation.
- 3.2.1. Hospital shall call the Donor Network West referral line (see section 2.1).
- 3.2.2. Hospital agrees to designate health care professionals available 24 hours per day to make a timely referral to Donor Network West if there is a death in the Hospital.
- 3.3. Donor Evaluation. Hospital will assist Donor Network West and will:
- 3.3.1. Provide access to and copies of the prospective donor's medical record in accordance with federal and state law and Sections 3.7 below.
- 3.4. Timely Pronouncement and Legal Documentation of Brain Death. Hospital will ensure timely and legal documentation of death, signed by hospital authorized personnel.
- 3.4.1. Hospital will ensure documentation of death declarations in patient's medical record with date, time and signature of physicians.
- 3.5. Donor Authorization.
- 3.5.1. Collaborative Support of Family and Notification of Donation Opportunity. Hospital shall work with Donor Network West to ensure that the appropriate person is notified about the anatomical gift made by the donor, or their option to donate organs, tissue, and eyes, whichever is applicable.
- 3.5.2. Designated Requestor. Donor Network West shall be solely responsible for making the request for donation from family members and/or person(s) authorized to make a gift of a prospective donor. Donor Network West shall make designated requestor training available to Hospital on request.
- 3.5.3. Family Support. OPO and Hospital staff, together part of the health care team providing support to families and facilitating the donation process, will use discretion and sensitivity with respect to the circumstances, views, and beliefs of the families of prospective donors.
- 3.5.4. First Person Authorization for Donation: If the prospective donor has a document of gift, and is medically suitable, Donor Network West and Hospital shall follow the wishes of the prospective donor as expressed.
- 3.6. Hospital Duties in Assisting the Recovery of Tissues from Prospective Donors.
- 3.6.1. Provision of Recovery Room. Provide an appropriate location, including, as applicable, an operating room or other adequate facility for recovery of anatomical gifts and personnel, as needed.
- 3.6.1.1. Donor Network West retains the option to transfer a prospective donor to another facility for tissue recovery if, in Donor Network West's reasonable judgment, Hospital does not have a recovery room available and one cannot be provided in a timely fashion without jeopardizing the viability of tissue. The transfer will be accomplished at Donor Network West's sole expense.
- 3.6.1.2. Access to Hospital Services. Provide access to hospital services such as morgue access, and recovery room availability on a 24/7 basis.
- 3.6.2. Physiological Support of the Prospective Donor. Hospital shall perform appropriate donor maintenance, pending the recovery of tissues, pursuant to guidelines provided by Donor Network West.
- 3.6.2.1. Assisting Donor Network West with the ordering of necessary donor evaluation laboratory tests and scheduling professional consult evaluations;
- 3.6.3. Provision of Internet Service. Hospital will provide Donor Network West with a wired/wireless secure Internet connection in or near the Critical Care units and Recovery Room.

- 3.7. Electronic Health Records. If Hospital implements an electronic health records system, Hospital will provide Donor Network West timely access to the patient records to facilitate all aspects of donation and death record reviews.

ARTICLE IV

Reimbursement

- 4.1. Hospital Reimbursement. Hospital agrees to provide Donor Network West with an itemized bill (request for reimbursement) for directed services incurred for all patients accepted by Donor Network West as donors within seven months of the close of the case. Failure to provide Donor Network West with a request for reimbursement within this time frame will result in the elimination of any liability on the part of Donor Network West for hospital services provided. Donor Network West agrees to pay Hospital the lesser of billed charges or the hospital reimbursement rate based on tissue recovery type as per the then current fee schedule, provided upon request.

ARTICLE V

Termination

- 5.1. Termination. This agreement shall stand as a document without expiration. Either party desiring to terminate this Agreement without cause shall provide as reasonable notice as is possible, but in no case less than one-hundred eighty (180) days' written notice to the other party. Such notice shall specifically state the reason for termination of the Agreement, and such party desiring to terminate this Agreement shall provide such documentation to the other party supporting the reason so stated.

ARTICLE VI

Miscellaneous

- 6.1. Emergency Preparedness. The parties shall each maintain an emergency preparedness plan that strives to ensure continuation of operations during emergency situations, in the event of a natural, technological or man-made disaster, and notify each other when emergency situations impact normal processes.
- 6.2. Indemnification. Each Party shall defend, indemnify, and hold the other party and its officers, employees, and agents harmless from and against any and all liability, loss, expense (including reasonable attorneys' fees), or claims for injury or damages arising out of the performance of this Agreement, but only in proportion to and to the extent such liability, loss, expense, attorneys' fees, or claims for injury or damages are caused by or result from the negligent or intentional acts or omissions of the indemnifying party and/or its officers, employees, and agents.
- 6.3. Insurance.
- 6.3.1. General and Professional Liability Insurance: Each party will obtain and maintain comprehensive general liability insurance (including coverage for professional liability) in connection with its obligations under this Agreement. Such insurance coverage shall be in amounts not less than \$1 million per claim/\$3 million annual aggregate, and coverage shall be insured through an insurer that is qualified to do business in the State of California. Each party shall bear its cost of such insurance, and certificates of insurance evidencing such coverage shall be made available to the parties upon their request. Any insurance required under this section may be obtained through a program(s) of self-insurance.
- 6.3.2. Workers' Compensation: Donor Network West is providing workers' compensation coverage pursuant to the State of California for its employees and contractors providing services under this agreement and can provide evidence of coverage as requested. Said policy shall contain, or be endorsed to contain, a waiver of subrogation against COUNTY and its agents, officers, officials, employees, and volunteers.
- 6.4. Compliance: Donor Network West and Hospital agree to comply with all federal, state, and local laws and regulations, which pertain to the performance of this Agreement, including, without limitation, applicable

regulations promulgated by OSHA, CMS, CDC, and FDA, as applicable. Hospital has no legal obligation to vaccinate Donor Network West staff. Furthermore, Donor Network West staff are not hospital employees and are not required to attend hospital orientation or other programs mandated for staff. Donor Network West is solely responsible for maintaining records for Donor Network West employees with regard to job competencies, training, immunizations, and medical testing. Donor Network West agrees to work cooperatively with Hospital with regard to facilitating Hospital's demonstrated compliance with those standards of care and quality promulgated by the Joint Commission, which applies to the performance of this Agreement. Both parties agree to work cooperatively to implement appropriate changes, correct deficiencies, and/or establish policies required and/or recommended by the inspecting agencies.

- 6.5. Confidentiality: Donor Network West is neither a contractor of nor a business associate to Hospital, and it is not a covered entity under HIPAA. Each party and its respective employees and assigns shall adhere to all applicable state and federal statutes and regulations regarding the confidentiality of patient information, including, but not limited to, information concerning serology results, donor status, and any and all information concerning the potential recipient(s).
- 6.6. Notices: All notices hereunder shall be in writing, delivered personally, by certified or registered mail, return receipt requested, or by overnight courier, and shall be deemed to have been duly given when delivered personally or when deposited in the United States mail, postage prepaid, or deposited with the overnight courier addressed as follows or such other addresses as may later be designated by the party.

If to Hospital:

Humboldt County Department of Health and Human Services – Behavioral Health
720 Wood Street
Eureka, CA 95501
Attn: Hospital Administration

If to Donor Network West:

Donor Network West
12667 Alcosta Blvd., Suite 500
San Ramon, CA 94583
Attn: Chief Executive Officer

- 6.7. Amendments. This Agreement may be amended or modified at any time, and such amendment must be in writing and signed by authorized representatives of both parties. The parties agree to amend this agreement to the extent amendment is required to comply with applicable federal and state laws and regulations and any changes thereto.
- 6.8. Governing Law. This Agreement shall be governed by and construed in accordance with the laws of the State of California and applicable federal law.
- 6.9. Severability. The provisions of this Agreement are severable. If any one or more provisions of this Agreement are held invalid, the remaining provisions shall continue in full force and effect.
- 6.10. Nuclear-Free Humboldt County Ordinance Compliance: By executing this Agreement, Donor Network West certifies that it is not a Nuclear Weapons Contractor, in that Donor Network West is not knowingly or intentionally engaged in the research, development, production or testing of nuclear warheads, nuclear weapons systems or nuclear weapons components as defined by the Nuclear-Free Humboldt County Ordinance. Donor Network West agrees to notify Hospital immediately if it becomes a Nuclear Weapons Contractor as defined above. Hospital may immediately terminate this Agreement if it determines that the foregoing certification is false or if Donor Network West subsequently becomes a Nuclear Weapons Contractor.
- 6.11. Counterparts. This Agreement, and any amendments hereto, may be executed in one (1) or more counterparts, each of which shall be deemed to be an original and all of which, when taken together, shall be deemed to be one (1) and the same agreement. This Agreement, and any amendments hereto, may be signed by manual or electronic signatures in accordance with any and all applicable local, state and federal laws, regulations and standards, and such signatures shall constitute original signatures for all purposes. A signed copy of this

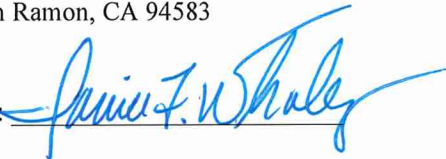
Agreement, and any amendments hereto, transmitted by email or by other means of electronic transmission shall be deemed to have the same legal effect as delivery of an original executed copy of this Agreement and any amendments hereto.

6.12. Each person executing this Agreement represents and warrants that he or she is duly authorized and has legal authority to execute and deliver this Agreement. Each party represents and warrants to the other that the execution and delivery of this Agreement and the performance of such party's obligations hereunder have been duly authorized.

IN WITNESS WHEREOF, by affixing their signature below, each of the parties has caused this Agreement to be executed on its behalf by its duly authorized representative, to be effective as of the last date written below.

Donor Network West

12667 Alcosta Blvd., Suite 500
San Ramon, CA 94583

By: 

Name: Janice F. Whaley

Title: President and CEO

Humboldt County's Inpatient Psychiatric Health Facility Hospital Address

720 Wood Street
Eureka, CA 95501

By: _____

Name: Rex Bohn, Chair

Humboldt County Board of Supervisors