*University Agreement No.*



**AGREEMENT OF INSTITUTIONAL AFFILIATION**

**between**

# Regents of the University of Minnesota (“University”)

**by and through Lions Gift of Sight (“LGS”), a program of the**

**University’s Medical School Department of Ophthalmology and Visual Neurosciences**

**and**

**(“Affiliate”)**

***THIS AGREEMENT OF INSTITUTIONAL AFFILIATION*** (“Agreement”) made between University and Affiliate is effective as of       (the “Effective Date”).

**RECITALS**

 **WHEREAS,** University and Affiliate wish to cooperate in the identification and referral of all potential eye donors to LGS for proper retrieval, processing, preservation, storage and distribution of ocular tissue for transplantation, research and education; and

 **WHEREAS**, University and Affiliate wish to work cooperatively in educating Affiliate staff, reviewing death records and maintaining potential donors.

 **NOW, THEREFORE,** the parties agree as follows:

**1. LGS Services and Responsibilities.** University, through LGS, shall:

 1.1 Provide 24-hour availability of eye bank staff and physician support to evaluate potential eye donations.

 1.2 Maintain its accreditation by the Eye Bank Association of America and comply with Food and Drug Administration regulations.

 1.3 Adhere to the Affiliate administrative, medical and nursing staff policies at all times.

 1.4 In the absence of an Affiliate staff person certified as a designated requestor, LGS, or its designee, will contact potential eye donor’s legal next of kin or authorized decision maker to request informed consent for eye donation.

 1.5 Arrange for the procurement of the eyes and transportation of the eyes to LGS.

 1.6 Provide all necessary instruments and supplies required for the procurement and shipping of the eyes.

 1.7 Reimburse Affiliate for reasonably necessary charges resulting from the eye recovery process.

 1.8 Determine medical suitability of potential eye donor.

 1.9 Send follow-up information to all donor families informing them of the outcome of each donation.

 1.10 Provide assistance as requested by Affiliate in the development of specific policies and procedures allowing for the unique features of the Affiliate donation program.

 1.11 Work in cooperation with the federally-designated organ procurement organization (“OPO”) and Affiliate’s designated tissue procurement organization to provide a comprehensive system for organ, tissue and eye donation, including the 24-hour shared Donor Referral Line (1-800-24-SHARE), and to provide education and awareness about organ, tissue and eye donation to Affiliate’s staff and medical professionals and to the public.

 1.12 Maintain confidentiality of all information gathered during the eye donation process. In accordance with Health Insurance Portability and Accountability Act (“HIPAA”) regulations, LGS will keep confidential all hospital and patient information including, but not limited to, Protected Health Information (“PHI”) reports, memos, and other data obtained from Affiliate or created by LGS.

**2. Affiliate Services and Responsibilities.** Affiliate, dedicated to increase the availability of eyes, tissue and organs for transplantation and serving families of potential donors, shall:

 2.1 Identify potential eye donors whose death is imminent or who have died in its facility and will notify LGS in a timely manner of all such potential eye donors by calling 1‑800-24-SHARE or another number provided by LGS.

 2.2 Provide the Donor Referral Line operator with potential donor’s age, date, time, cause/nature of death, donor designation status if known (e.g. via a healthcare directive) and medical history in order to enable LGS to evaluate suitability of eye donation from the potential donor.

 2.3 Provide to LGS accessibility to (a) potential donor’s medical records (paper and electronic), (b) potential donor’s next of kin contact information, (c) Affiliate health care professionals, and (d) computer, copy and fax machine, to the extent necessary to carry out procurement and donation activities once designated donation status is verified or authorization for donation and the release of medical records have been obtained from the potential donor’s legal next of kin.

 2.4 Direct its staff and medical professionals to maintain the eye tissue of potential donors by using measures according to training and information provided by LGS to Affiliate for inclusion in Affiliate’s donation policies and procedures, and in staff and medical professionals donation education.

 2.5 Allow LGS certified procurement technicians access to facilities suitable for retrieving donor tissue.

 2.6 Provide information concerning Affiliate’s administrative, medical and nursing staff policies and procedures to LGS upon request.

 2.7 Work cooperatively with LGS in educating Affiliate’s staff about policies, procedures and issues related to eye, organ and tissue donation and all aspects of the eye donation process, including referral of potential donors, donation coordination and recovery of donation, promoting awareness of the eye donation program among its staff, and allowing LGS to submit, review and approve content and materials related to eye donation used for education and promotion and recognition of donation with Affiliate’s staff, medical professionals, patients, donor family members, potential donor family members and the public.

 2.8 Work cooperatively with LGS in reviewing death records to improve identification of potential donors including, at LGS’s request, providing a written report of all deaths to LGS for purposes of monitoring, evaluating and improving the eye donation program.

 2.9 Include LGS in the development, revision and implementation of eye, tissue or organ donation policies. Affiliate’s policies will be consistent with relevant state and federal laws and regulations.

**3. Insurance and Indemnification.**

 3.1 University shall maintain professional and general liability insurance in minimum amounts of $1,000,000 for each claim/$3,000,000 annual aggregate. Upon request, University will provide to Affiliate a certificate of insurance evidencing such coverage.

 3.2 Affiliate shall maintain professional and general liability insurance or appropriate self-insurance coverage in minimum amounts of $1,000,000 for each claim/$3,000,000 annual aggregate. Upon request, Affiliate will provide to University a certificate or memorandum of insurance evidencing such coverage.

 3.3 Each party agrees that it will be responsible for its own acts and the results thereof to the extent authorized by law and shall not be responsible for the acts of the other party and the results thereof. University’s liability is limited to the extent of its insurance coverage pursuant to the Minnesota Tort Claims Act, Minn. Stat. §3.736.

**4. Other Terms.**

 4.1 The initial term of this Agreement shall begin on the Effective Date and shall end two years thereafter. Following the initial term, this Agreement shall continue for successive terms of one year each, unless either party provides written notice to the other party at least ninety (90) days in advance of the end of the initial term or a renewal term, as the case may be, of its election not to renew this Agreement. In addition, if either party is in default under this Agreement and fails to cure such default within sixty (60) days following receipt of notice from the other party describing the default, then the non-defaulting party may terminate this Agreement upon at least thirty (30) days’ written notice to the other party.

 4.2 The parties recognize that the goal of their relationship is to best serve eye donors, families, recipients and the community, and believe that this goal can best be met by ensuring consistency in how ocular tissue is retrieved, processed, preserved, stored and distributed. Accordingly, during the term of this Agreement, Affiliate agrees that it will not enter into a contract with another organization to serve as the hospital’s eye bank under 42 CFR § 482.45(a)(2).

 4.3 All notices, certificates or other communications rendered shall be sufficiently given when personally delivered or on the date which is two days after being mailed postage prepaid to the representatives of the parties at their respective places of business as herein set forth:

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| If to Affiliate, to:     Attn:                     with a copy to (which shall not constitute notice):     Attn:                      | If to University, to:Lions Gift of SightAttn: Executive DirectorUniversity of Minnesota1000 Westgate Drive, Suite 260St. Paul, MN 55114 with a copy to (which shall not constitute notice):Academic Health Center General CounselUniversity of Minnesota426 Church Street SEMMC 501Minneapolis, MN 55455 |

 4.4 The parties shall comply with all applicable laws governing the assurance of equal opportunity and shall not discriminate in violation of law in the performance of this Agreement with regard to race, color, creed, religion, national origin, gender, age, marital status, disability, public assistance status, veteran status, sexual orientation, gender identity or gender expression.

 4.5 Each party has in place a compliance process or program (“Program”), the goal of which is to comply with federal, state and local laws and regulations. Each party’s Program includes a commitment to uphold a high standard of ethical and legal business practices to prevent misconduct. Through the implementation of this Agreement, each party acknowledges its commitment to compliance and agrees to conduct all transactions that occur pursuant to this Agreement in accordance with all applicable laws, rules and regulations and with the underlying philosophy and objectives of each party’s Program. By executing this Agreement, University and LGS represent and warrant that they are not, and have not been, excluded from participation in any federally and/or state funded health care programs, including Medicare and Medicaid. In the event University or LGS are excluded from participation in any federally and/or state funded health care programs during the term of this Agreement, University and LGS agree to notify Affiliate within five (5) business days or less of the exclusion.

4.6 Nothing in this Agreement is intended or should be construed as creating the relationship of copartners, joint ventures, or an association between the parties, nor shall any party, its employees, agents, students or representatives be considered employees, agents or representatives of any other party.

 4.7 It is specifically agreed that neither party shall be responsible for costs or expenditures incurred by the other, except as expressly provided for in this Agreement.

 4.8 This Agreement supersedes and replaces any previous verbal or written agreements between the parties regarding the subject matter herein.

 4.9 The parties agree that if any term or provision of this Agreement is declared by a court of competent jurisdiction to be illegal or in conflict with any law, the validity of the remaining terms and provisions shall not be affected, and the rights and obligations of the parties shall be construed and enforced as if this Agreement did not contain the particular term or provision held to be invalid.

 4.10 This Agreement shall be governed by Minnesota law, and all disputes shall be venued in Hennepin County, Minnesota.

 4.11 Subject to the written authorization by appropriate representatives of University and Affiliate, addenda to this Agreement may be developed to facilitate day-to-day and year-to-year execution of the goals of this Agreement. Each Addendum shall be in writing and executed by an authorized representative of each of the parties. To the extent an Addendum is not properly executed by persons authorized to do so and to the extent it conflicts or contradicts the terms herein, it shall be considered invalid.

*[Execution Page Follows]*

 **IN WITNESS WHEREOF**, each individual signing below hereby represents and warrants being duly authorized to execute and deliver this Agreement on behalf of the respective party.

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| By: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Name:      Title:      Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_By: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Name:      Title:      Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | **Regents of the University of Minnesota**By: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Name: Sean M. PoppoffTitle: Executive Director, Lions Gift of SightDate: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_By: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Name: Jakub Tolar, MD, PhDTitle: Dean, Medical School Vice President for Clinical AffairsDate: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

***Note: This agreement to be executed by Affiliate before University representatives begin the execution process.***