ORGAN PROCUREMENT ORGANIZATION & TISSUE BANK – SUPPLEMENTAL APPLICATION

This is a Supplemental Application which becomes part of the Lexington Miscellaneous Facilities Application. The Applicant represents that the statements and facts are true and no material facts have been suppressed or misstated. If a policy is issued, this Supplemental Application will become part of the policy as if physically attached. Therefore, it is mandatory that all questions be answered completely. Completion of this Supplemental Application does not bind coverage.

General Information

Applicant's Name:

Web Site:

Business Address:
Mailing Address:

Date Business Started: Employer Federal Tax ID #: Telephone #:

Producer Name:

Address:

Telephone:

1. Enter the Processing percentages:

Direct Processing

Indirect Processing

Total

2. Please indicate all of the operations at the applicant's facility:

OPO
Eye Procurement
Tissue Procurement
Tissue Processing
Tissue Labeling
Cord Blood
Other

Tissue Distribution
Tissue Storage
Laboratory Testing In-house for Internal Purposes
Laboratory Testing In-house for Other Entities
Operating Room for Procurement

3. Organ Exposure Data: Please indicate the total number of historical, current and projected organ donors listed by organ type:

Organs Procured (by type)					Current Year	Projected Next 12 Months
Other						

Other Description:

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4. Tissue Exposure Data: Please indicate the total number of historical, current and projected tissue donors by tissue type):

Tissues Procured (by type)					Current Year	Projected Next 12 Months
Tissue Processed (by type)						
Tissue Provided For Transplant (by type)						
# of Tissue Units Returned						

5. Revenue Data: Describe the applicant's annual revenue (historical, current and projected) by category:

Sources of Revenue					Current Year	12 Months Projected Revenue
Organ Procurement						
Tissues Procurement						
Eye Procurement						
Direct Processing						
Product Sales						
Referral Services						
Tissue Storage/Distribution						
Research/Grant Revenues						
Total						

6. If there any operation or affiliation between the applicant's facility and another organization or firm, enter the name beside the category:

Name of Entity

Donor Hospital
Transplant Center
Tissue Processing Center
Heart Valve Recovery
Tissue Storage/Distribution
Transportation
Research Affiliation
Educational Affiliation
Other

If yes to any of the above, explain:

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7. Does the applicant's facility participate on the AOPO Quality Council?

8. Does the applicant have an Infection Control Program implemented?

9. Are the applicant's policies and procedures reviewed/revised biannually?

10. Has the applicant's facility been involved in any tissue FDA recalls?

If yes, please explain here:

11. Has the applicant's facility initiated any voluntary tissue recalls in the past 5 years?
If yes, please provide details:

Dates	Volume of Tissues Recalled	Explanation

12. Has the applicant's facility received any FDA Survey Reports, 483 Observation Reports and/or Warning Letters within the past three years? □ Yes □ No

If so, explain and provide copies of each.

13. Professional Employees/Independent Contractors:

(a) Does the applicant employ physicians?

(b) Does the applicant have physician position descriptions?

(c) Does the applicant have an implemented credentialing policy?

(d) Does the applicant perform primary source verification of credentials?

(e) Does the applicant require evidence annually that physicians carry their own malpractice insurance?

If yes, does the applicant require minimum coverage?

If yes, give required amounts:

(f) Does the applicant require certification of procurement coordinators?
If yes, specify type of certification by certifying organization:

If yes, what is the required time frame from commencement of employment?

14. Please complete the following to indicate the type(s) of Informed Consents Obtained by the applicant's facility:

	Witnessed	Recorded	Retained if Recorded	Describe Consent Process
Organ Procurement				
Tissue Procurement by The applicant's Facility				
Tissue Procurement on behalf of Another Facility				
Eye Procurement by The applicant's Facility				
Eye Procurement on behalf of Another Facility				

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15. Please enter the test name for any of the following screening tests that the applicant's facility utilizes:

	Test Name
HIV	
HBV (Hepatitis B)	
HCV (Hepatitis C)	
HTLV (Leukemia)	
RPR (Syphilis)	
CMV (Liver Disease)	
Other	

16. Does the applicant accept HIV Positive Donors?

If yes, describe the process/documentation of informing transplant surgeon and recipient:

Does the transplant surgeon sign a written attestation acknowledging the donor is HIV positive?

17. Are any tissues procured / recovered from outside the U.S?

If yes, please explain:

18. Are any non-human tissues used in any way at the facility?

If yes, please explain:

19. If the applicant's facility utilizes any non-allograft materials (i.e. metal screws – manufactured or distributed), please explain or enter 'N/A.

20. In how many states does the applicant's facility operate? (indicate # of states):

List the number of donations by state.

State	Donations	State	Donations	State	Donations

21. If the applicant performs laboratory testing in-house, specify tests performed, if not, enter 'N/A':

Does the applicant provide laboratory testing for other facilities? Y/N
If yes, please specify tests performed and provide copy of contract:

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22. Does the applicant outsource any laboratory testing? Y/N

If yes, please complete the following and provide copy of contract(s):

Name and Address of the Facility	Test Names	Total Number of Tests

23. Does the applicant procure split livers?

If so, how many the past two years?

24. Does the applicant procure, process, and/or distribute dura mater?

25. Does the applicant accept John Doe Donors?

26. Does the applicant participate in a living donor program?

If yes, please complete the following:
Number of living donors in the past two years;

Number projected next year:

The facility's role in the program:

Does the applicant obtain written consent?

If the applicant obtains written consent, describe the process and nature of consent.

If the facility agreed to unilaterally hold harmless or indemnify others under contract, describe and include a copy.

27. Does the facility screen for history of smallpox vaccination or exposure to someone with complications from a recent smallpox vaccination?
Please attach a list of vaccinations included in the screening process.

28. If the applicant's facility is involved in any reproductive medicine, please explain.

29. Does the applicant's facility place all organs through UNOS?

If not, does it have a protocol for ensuring compatibility?

If yes, provide copy.

Please provide a copy of the following:

(1) FDA inspection reports, 483 Observation Reports, Warning Letters (last 3 years).
(2) State licensure/state certificates.
(3) AATB accreditation certificate, survey report, and status of most recent recommendations.
(4) AOPO accreditation certificate, survey report, and status of most recent recommendations.

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(5) EBAA accreditation certification, survey report, and status of most recent recommendations.
(6) Center of Medicare & Medicaid (DHHS) reports/certificates.
(7) ISO certification (if applicable).
(8) All marketing material.
(9) Donor evaluation and screening tool with companion policy and procedures.
(10) Donor exclusion criteria.
(11) Consent form with companion policy and procedures.
(12) Criteria for blood samples.
(13) Criteria for tissue cultures.
(14) List of Hospital and transplant center affiliates.

30. LOSS HISTORY

(1) Submit company produced 5 year loss history with a clearly marked valuation date with breakdowns of incurred losses (including paid and reserves for indemnity and expenses), current status and an explanation for each loss (with detailed explanations for large losses).

(2) Has the applicant's facility had any claims (formal or informal; written or non-written) regarding informed consent?
If yes, please explain within Loss History attachment.

(3) Is the applicant aware of any incidents that may give rise to any future claim?

THE UNDERSIGNED DECLARES THAT THE STATEMENTS SET FORTH HEREIN ARE TRUE. THE UNDERSIGNED AGREES THAT IF THE INFORMATION SUPPLIED ON THIS SUPPLEMENTAL APPLICATION CHANGES BETWEEN THE DATE OF THIS SUPPLEMENTAL APPLICATION AND THE EFFECTIVE DATE OF THE INSURANCE, HE/SHE (UNDERSIGNED) WILL IMMEDIATELY NOTIFY THE COMPANY OF SUCH CHANGES, AND THE COMPANY MAY WITHDRAW OR MODIFY ANY OUTSTANDING QUOTATIONS, AUTHORIZATION OR AGREEMENT TO BIND THE INSURANCE.

SIGNING OF THIS SUPPLEMENTAL APPLICATION DOES NOT BIND THE APPLICANT OR THE COMPANY TO COMPLETE THE INSURANCE, BUT IT IS AGREED THAT THIS SUPPLEMENTAL APPLICATION SHALL BE PART OF THE BASIS OF THE CONTRACT SHOULD A POLICY BE ISSUED, AND THIS SUPPLEMENTAL APPLICATION WILL BE ATTACHED TO AND BECOME PART OF THE POLICY.

ALL WRITTEN STATEMENTS AND MATERIALS FURNISHED TO THE COMPANY IN CONJUNCTION WITH THIS SUPPLEMENTAL APPLICATION ARE HEREBY INCORPORATED BY REFERENCE INTO THE APPLICATION AND MADE A PART HEREOF.

THIS SUPPLEMENTAL APPLICATION MUST BE SIGNED BY AN OFFICER OR PRINCIPAL OF THE APPLICANT.

Name of Applicant:_____

Title: _____

Signature: _____

Date: _____