SPG SPECIALTY PROGRAM GROUP

ORGAN AND TISSUE FACILITY APPLICATION

PRODUCER INFORMATION

Agency Name _____

Mailing Address _____ City/State/Zip _____

Producer Name _____ Telephone _____ Fax _____

APPLICANT INFORMATION

Named Insured _____ County _____

Primary Location _____ City/State/Zip _____

CEO _____ Risk Manager _____Website: _____

Authorized representative for insurance matters: _____Telephone _____

Email Address of Authorized Representative: _____

FACILITY INFORMATION

1. How many years has the facility been in operation? _____

2. **Ownership and Control**

   ☐ Governmental
   ☐ Individual
   ☐ Partnership
   ☐ Corporation
   ☐ Other (explain)_____

   Tax Status

   ☐ For Profit
   ☐ Not for Profit
   ☐ Medicare Approved
   ☐ Charitable

3. Please indicate all of the operations at your facility:

   ☐ Organ Procurement
   ☐ Living Donor Program
   ☐ Eye Procurement
   ☐ Heart Valve Recovery
   ☐ Heart Valve Processing
   ☐ Tissue Procurement
   ☐ Tissue Processing
   ☐ Other (describe) _____
   ☐ Other (describe) _____

   ☐ Tissue Labeling
   ☐ Tissue Distribution
   ☐ Tissue Storage
   ☐ Laboratory Testing Inhouse for Internal Purposes
   ☐ Laboratory Testing Inhouse for other Entities
   ☐ Research

INSURANCE COVERAGE REQUEST

1. Requested Effective Date _____

2. Requested Limits

   Professional Liability $_____ /$_____ ☐Claims Made Retroactive Date_____
   per claim aggregate

   General Liability $_____ /$_____ ☐Claims Made Retroactive Date_____
   per claim aggregate ☐Occurrence Coverage

3. Deductible ☐ None

   Professional Liability $_____ /$_____ General Liability $_____ /$_____
   per claim aggregate per claim aggregate

4. *Self Insured Retention $_____ /$_____ *(*refer to application guidelines for required attachments)*
   per claim aggregate

   a) What coverage does the SIR contemplate? ☐ Professional Liability ☐ GL ☐ Other _____
   b) Is there an Insurance Trust? ☐ Yes ☐ No
   c) Is there an Insurance Captive? ☐ Yes ☐ No
   d) What organization handles claims for the SIR? _____
   e) What legal firm is responsible for defending claims against the insured? _____
   _____

5. ☐ Straight Excess Liability ☐ *Excess Umbrella Liability *(*refer to application guidelines for required attachments)*
   Limits $_____/$_____ Retroactive Date _____

6. ☐ Employee Benefits Administration Liability
   Total number of employees _____ Retroactive Date: _____

INSURANCE HISTORY

Complete the following professional liability insurance history:

***Current Carrier** _____ ☐ Claims Made ☐ Occurrence
Effective Date _____ Expiration Date_____ Retroactive Date _____
Limits $_____/$_____ ☐ Deductible/SIR $ _____
Expiring premium(s) $ _____
(**attach copy of current policy - see application guidelines)*

1st Prior Carrier _____ ☐ Claims Made ☐ Occurrence
Effective Date _____ Expiration Date_____ Retroactive Date _____

2nd Prior Carrier _____ ☐ Claims Made ☐ Occurrence
Effective Date _____ Expiration Date_____ Retroactive Date _____

4. Revenue Data: Describe your annual revenue (historical, current and projected) by category:

Source of Receipts or Revenue	Year: _____ ☐ Fiscal ☐ Calendar	Year: _____ ☐ Fiscal ☐ Calendar	Year: _____ ☐ Fiscal ☐ Calendar	Year: _____ ☐ Fiscal ☐ Calendar	Current Year: _____ ☐ Fiscal ☐ Calendar	Projected Next 12 Months
Organ Procurement						
Tissue Procurement						
Eye Procurement						
Direct Processing						
Product Sales						
Referral Services						
Tissue Storage/Distribution						
Research/Grant Revenues (specify):						
Other (specify)						
Other (specify)						
Other (specify)						
Total Company Revenue						
Total Number of Donors						
Number of Living Donors						

5. Please list the states you operate in, the percentage of revenue per state and indicate what percent is organ and tissue.

State Operating In	**Percentage of Revenue**	**Percentage Organ**	**Percentage Tissue**

6. Are you accredited by AOPO (Association of Organ Procurement Organizations) and/or AATB (American Association of Tissue Banks)? ☐ Yes ☐ No

7. If "Yes" to question 6, Does your facility participate on the AOPO Quality Council? ☐ Yes ☐ No

8. If "Yes" to question 6, Does your facility participate on the AATB Quality Assurance Task Force? ☐ Yes ☐ No

9. Are you accredited by EBAA (Eye Bank Association of America)? If you do not procure eyes, select Not Applicable. ☐ Yes ☐ No ☐N/A

10. Is your laboratory accredited by CAP (College of American Pathologists)? If you do not have a laboratory, select Not Applicable. ☐ Yes ☐ No ☐N/A

11. Is your laboratory accredited by ASHI (American Society for Histocompatability and Immunogenetics)? If you are not involved in the laboratory science of histocompatibility and immunogenetics, select Not Applicable. ☐ Yes ☐ No ☐N/A

12. Are you ISO certified? ☐ Yes ☐ No

13. Has your facility been surveyed by FDA within the past three years? ☐ Yes ☐ No

14. If your facility has been surveyed by FDA with the past three years, did you receive Warning Letters? If yes, please attach details. ☐ Yes ☐ No

PROFESSIONAL EMPLOYEES/INDEPENDENT CONTRACTORS

1. Indicate below the number of each type of professional employed or contracted by the entity:

	Employees	**Independent Contractors**	**Specialty**
*Employed Physician			
*Employed Resident			
Nurse Anesthetist			
Nurse Midwife			
Nurse Practitioner			
Physician Assistant			
Other:			

2. Is coverage being requested for anyone listed above? ☐ Yes ☐ No

3. Does any physician or allied healthcare professional have coverage independent of the group? ☐ Yes ☐ No

4. If "Yes", are annual certificates of insurance required for proof of professional liability coverage ☐ Yes ☐ No

5. If "Yes" , are specific limits required? Limits required: _____ ☐ Yes ☐ No

6. Are new practitioners proctored? ☐ Yes ☐ No

7. Are credentials for physicians and allied healthcare professionals checked and approved prior to joining the group? ☐ Yes ☐ No
8. Is there a probationary period? ☐ Yes ☐ No
9. Are all physician and allied healthcare professional's privileges reviewed at least once every two years? ☐ Yes ☐ No
10. Are all foreign medical graduates certified by the Educational Council for Foreign Medical School Graduates or have they passed the FLEX? ☐ Yes ☐ No
11. Do you require clinical staff to be certified by AATB? ☐ Yes ☐ No
    If you do not procure tissue, select Not Applicable ☐ Not Applicable
12. If "Yes" to number 11, what percentage of eligible staff are certified by AATB? _____%
13. Do you require clinical staff to be certified by NATCO? ☐ Yes ☐ No
    If you do not procure organs, select Not Applicable ☐ Not Applicable
14. If "Yes" to number 11, what percentage of eligible staff are certified by NATCO? _____%
15. Do you require clinical staff to be certified by EBAA? ☐ Yes ☐ No
    If you do not procure eyes, select Not Applicable ☐ Not Applicable
16. If "Yes" to number 11, what percentage of eligible staff are certified by EBAA? _____%
17. Do you utilize independent non-physician contractors for organ procurement? ☐ Yes ☐ No
18. Do you utilize independent non-physician contractors for tissue procurement? ☐ Yes ☐ No
19. Do you or any of its subsidiaries have a contract with or provide services to any correctional facilities which includes city or county jails, prisons, juvenile detention and youth correctional facilities? ☐ Yes ☐ No
20. Do you or any of its subsidiaries provide services to professional athletes or celebrities? ☐ Yes ☐ No

CONTRACTS

1. Has your facility agreed to unilaterally hold harmless or indemnify others under contract? ☐ Yes ☐ No
2. If lab work is subcontracted, is there a formal contract with the lab? ☐ Yes ☐ No
3. If there is a formal contract with a lab, does/do the contract/contracts include hold harmless clause indemnifying the OPO or tissue bank? ☐ Yes ☐ No

RISK MANAGEMENT

1. Is there an individual who is designated with the job title and role of OPO Risk Manager? ☐ Yes ☐ No
   Risk Manager Name: _____
2. Is there a written, formalized Risk Management plan? ☐ Yes ☐ No
3. Is this plan regularly reviewed for effectiveness and/or any necessary changes? ☐ Yes ☐ No
   If "Yes", how often is the plan reviewed? _____
4. Is there an ongoing Quality Assessment or Improvement plan? ☐ Yes ☐ No

INFORMED CONSENT

1. Is informed consent obtained for Organ Procurement? ☐ Yes ☐ No
2. Is informed consent obtained for tissue procurement by your facility? ☐ Yes ☐ No
3. Is informed consent obtained for tissue procurement on behalf of another facility? ☐ Yes ☐ No
4. Is informed consent obtained for eye procurement by your facility? ☐ Yes ☐ No
5. Is informed consent obtained for eye procurement on behalf of another facility? ☐ Yes ☐ No
6. Is informed consent obtained for heart valve replacement on behalf of another facility? ☐ Yes ☐ No
7. Do you have written policy and procedure for obtaining consent? ☐ Yes ☐ No
8. In seeking informed consent, is the following information provided to the person(s) being approached for consent: Identification of specific organs and/or tissues (including cells) that are being requested for donation. ☐ Yes ☐ No
9. In seeking informed consent, is the following information provided to the person(s) being approached for consent: An explanation that the retrieved organs/tissues may be used for transplantation, therapy, medical research, or educational purposes, if likely. ☐ Yes ☐ No
10. In seeking informed consent, is the following information provided to the person(s) being approached for consent: An explanation that tissue transplantation may include reconstructive and aesthetic surgery, if likely. ☐ Yes ☐ No
11. Do you procure eyes from medical examiner cases under implied consent? ☐ Yes ☐ No

DONOR EVALUATION AND SCREENING

1. Do you have formal policies and procedures that require donor evaluation and screening? ☐ Yes ☐ No
2. Do you have formal criteria for acceptance of donors? ☐ Yes ☐ No
3. Do you have formal criteria for exclusion of donors? ☐ Yes ☐ No
4. Do you have formal policies and procedures that require confidentiality? ☐ Yes ☐ No
5. Do you require NAT testing for HIV? ☐ Tissue Donors ☐ Organ Donors
6. Do you accept HIV positive donors for transplantation? ☐ Yes ☐ No
7. If "Yes" to question 6, does the transplant surgeon sign a written attestation acknowledging the donor is HIV positive? ☐ Yes ☐ No
8. Do you accept hepatitis C positive donors? ☐ Yes ☐ No
9. Do you require NAT testing for hepatitis C virus? ☐ Tissue Donors ☐ Organ Donors
10. If "Yes" to question 9, does the transplant surgeon sign a written attestation acknowledging the donor is HCV positive? ☐ Yes ☐ No
11. Do you require NAT testing for West Nile Virus? ☐ Tissue Donors ☐ Organ Donors ☐ Yes ☐ No
12. Do you accept John Doe donors? ☐ Yes ☐ No
13. Does your facility ever place organs in the United States, outside the United Network for Organ Sharing (UNOS)? ☐ Yes ☐ No
14. If "Yes" to question 13, do you have a policy and procedure for ensuring compatibility? ☐ Yes ☐ No

ORGAN AND TISSUE RECOVERY

1. Do you have written policies and procedures on donor identification? ☐ Yes ☐ No
2. Do you have written policies and procedures on physical assessment? ☐ Yes ☐ No
3. Do you have written policies and procedures on organ donor management? ☐ Yes ☐ No
4. Do you have written policies and procedures on documentation of all donor medications and fluids? ☐ Yes ☐ No
5. Do you have written policies and procedures on all donor lab tests, disposition, reports, and communication of relevant findings? ☐ Yes ☐ No
6. Do you have written policies and procedures on autopsy findings and communication of relevant findings? ☐ Yes ☐ No
7. Do you have written policies and procedures on documentation of quality of organs and tissues procured? ☐ Yes ☐ No
8. Do you have written policies and procedures on documentation of procurement complications and deviations from expected events? ☐ Yes ☐ No
9. Do you have written policies and procedures on verification of procured organs and tissues as per consent? ☐ Yes ☐ No
10. Do you have written policies and procedures on documentation of condition of donor following procurement of organs, tissue and eyes? ☐ Yes ☐ No

ORGAN DISTRIBUTION

1. Do you have written policies and procedures on verification/documentation of compatible blood type for organ donor/recipient? ☐ Yes ☐ No
2. Do you have written policies and procedures on confirmation of which lung and/or kidney provided to which recipient? ☐ Yes ☐ No
3. Do you have written policies and procedures on labeling and distribution? ☐ Yes ☐ No
4. Do you have written policies and procedures on compliance with organ allocation/distribution according to UNOS policy? ☐ Yes ☐ No

LIVING DONORS

1. Do you participate in a living donor program? ☐ Yes ☐ No
2. If participating in a living donor program, do you obtain a written general consent? ☐ Yes ☐ No
3. If participating in a living donor program, do you obtain a surgical consent? ☐ Yes ☐ No
4. If participating in a living donor program, do you maintain a registry for matching? ☐ Yes ☐ No

TISSUE SUPPLEMENT (This section applies to Tissue Processors only.) ☐ Not Applicable

1. Does your facility process and distribute fresh osteoarticular grafts? ☐ Yes ☐ No
2. If "Yes" to question 1, do you require microbiological testing? ☐ Yes ☐ No
3. If "Yes" to question 1, do you require surgeon's attestation regarding potential risk ☐ Yes ☐ No

4. Has your facility been involved in any FDA tissue recalls in the past 5 years? ☐ Yes ☐ No

5. If "Yes", please explain (include dates, volume of tissue, and reason):

_____

6. Has your facility initiated any voluntary tissue recalls in the past 5 years? ☐ Yes ☐ No

7. If "Yes", please explain (include dates, volume of tissue, and reason):

_____

8. Has your facility been surveyed by FDA within the past three years? ☐ Yes ☐ No

   If "Yes", please list date(s) of survey: _____ _____ _____

   If "Yes", did you receive:
   - ☐ Establishment Investigation Report (EIR) ☐ Yes ☐ No
   - ☐ 483 Observations ☐ Yes ☐ No If "Yes", resolved? ☐ Yes ☐ No
   - ☐ Warning Letters ☐ Yes ☐ No If "Yes", resolved? ☐ Yes ☐ No

   Please summarize nature of Warning Letter:

   _____

   (PLEASE PROVIDE A COPY OF EACH FDA REPORT AND CURRENT STATUS OF OBSERVATIONS/WARNINGS.)

9. Is your facility involved in any reproductive medicine? ☐ Yes ☐ No

   If "Yes", please explain: _____

10. Are any tissues procured/recovered from outside the US? ☐ Yes ☐ No

    If "Yes", please explain: _____

11. Are any non-human tissues used in any way at the facility? ☐ Yes ☐ No

    If "Yes", please explain: _____

12. Does your facility utilize any non-allograft materials (i.e. metal screws-manufactured or distributed)? ☐ Yes ☐ No
    If "Yes", please explain: _____

13. Do you procure, process and/or distribute dura mater? ☐ Yes ☐ No

LOSS HISTORY

1. Submit company produced 10 year loss history that includes: Date Reported, breakdown of incurred losses, current status, and an explanation for each loss (with detailed explanations for large losses).

2. Has your facility had any claims (formal or informal; written or non-written) regarding informed consent? ☐ Yes ☐ No

3. Are you aware of any incident that may give rise to any future claim? ☐ Yes ☐ No

   If "Yes", please provide details: _____

DOCUMENTS

Please provide a copy of the following documents:

1. FDA inspection reports, 483 Observation Reports, Warning Letters (last 3 years) ☐ Attached
2. State licensure/State certificates ☐ Attached
3. AATB accreditation certificate, survey report, and status of most recent recommendations. ☐ Attached
4. AOPO accreditation certificate, survey report, and status of most recent recommendations. ☐ Attached
5. EBAA accreditation certificate, survey report, and status of most recent recommendations. ☐ Attached
6. Center of Medicare & Medicaid (DHHS) reports/certification ☐ Attached
7. ISO certification (if applicable) ☐ Attached
8. Donor evaluation and screening tool with companion policy and procedures ☐ Attached
9. Donor criteria _____ ☐ Attached
10. Donor exclusion criteria ☐ Attached
11. Consent form with companion policy and procedures ☐ Attached
12. Policy & procedure for organ distribution outside of UNOS registry if applicable ☐ Attached

NOTICE

To All Prospective Insureds: Any person who knowingly, and with intent to defraud any insurance company or other person, files an application for insurance or statement of claim containing any materially false information, or, for the purpose of misleading, conceals information concerning any fact material thereto, may commit a fraudulent insurance act which is a crime and subjects such person to criminal and civil penalties in many states.

To Prospective Insureds In:

Notice to California Applicants: For your protection California law requires the following to appear on this form: Any person who knowingly presents false or fraudulent information to obtain or amend insurance coverage or to make a claim for the payment of a loss is guilty of a crime and may be subject to fines and confinement in state prison.

Notice to Colorado Applicants: It is unlawful to knowingly provide false, incomplete or misleading facts or information to an insurance company for the purpose of defrauding or attempting to defraud the company. Penalties may include imprisonment, fines, denial of insurance and civil damages. Any insurance company or agent of an insurance company who knowingly provides false, incomplete, or misleading facts or information to a policyholder or claimant for the purpose of defrauding or attempting to defraud the policyholder or claiming with regard to a settlement or award payable for insurance proceeds shall be reported to the Colorado Division of Insurance within the Department of Regulatory Agencies.

Notice to District of Columbia and Louisiana Applicants: "Any person who knowingly presents a false or fraudulent claim for payment of a loss or benefit or knowingly presents false information in an application for insurance is guilty of a crime and may be subject to fines and confinement in prison."

Notice to Florida Applicants: Any person who knowingly and with intent to injure, defraud or deceive any insurance company, files a statement of claim containing any false, incomplete, or misleading information is guilty of a felony of the third degree.

Notice to Oklahoma Applicants: Any person who knowingly, and with intent to injure, defraud or deceive any insurer, files a statement of claim containing any false, incomplete or misleading information is guilty of a felony. **(Note: In Oklahoma the language must appear on the face of the policy, application and claims forms in 10 pt. font or larger)**.

Notice to Kansas Applicants: An act committed by any person who, knowingly and with intent to defraud, presents, causes to be presented or prepares with knowledge or belief that it will be presented to or by an insurer, purported insurer, broker or any agent thereof, any written statement as part of, or in support of, an application for the issuance of, or the rating of an insurance policy for personal or commercial insurance, or a claim for payment or other benefit pursuant to an insurance policy for commercial or personal insurance which such person knows to contain materially false information concerning any fact material thereto; or conceals, for the purpose of misleading, information concerning any fact material thereto.

Notice to Maine, Tennessee, Virginia and Washington Applications: It is a crime to knowingly provide false, incomplete or misleading information to an insurance company for the purpose of defrauding the company. Penalties may include imprisonment, fines and/or denial of insurance benefits.

Notice to Maryland Applicants: Any person who knowingly or willfully presents a false or fraudulent claim for payment of a loss or benefit or who knowingly or willfully presents false information in an application for insurance is guilty of a crime and may be subject to fines and confinement in prison.

Notice to New Hampshire Applicants: Any person who, with a purpose to injure, defraud or deceive an insurance company, files a statement of claim containing any false, incomplete or misleading information is subject to prosecution and punishment for insurance fraud as provided in RSA 638:20.

Notice to New York Applicants: Any person who knowingly and with intent to defraud any insurance company or other person files an application for insurance or statement of claim containing any materially false information, or conceals for the purpose of misleading, information concerning any fact material thereto, commits a fraudulent insurance act, which is a crime, and shall also be subject to a civil penalty not to exceed $5,000 and the stated value of the claim for each such violation.

Notice to New York Applicants (Fire insurance applications): Any person who knowingly and with intent to defraud any insurance company or other person files an application for insurance containing any false information, or conceals for the purpose of misleading, information concerning any fact material thereto, commits a fraudulent insurance act, which is a crime. The proposed insured affirms that the foregoing information is true and agrees that these applications shall constitute a part of any policy issued whether attached or not and that any willful concealment or misrepresentation of a material fact or circumstances shall be grounds to rescind the insurance policy.

Notice to New York Applicants (Automobile): Any person who knowingly makes or knowingly assists, abets, solicits or conspires with another to make a false report of the theft, destruction, damage or conversion of any motor vehicle to a law enforcement agency, the department of motor vehicles or an insurance company, commits a fraudulent insurance act, which is a crime, and shall also be subject to a civil penalty not to exceed $5,000 and the value of the subject motor vehicle or stated claim for each violation."

Notice to Pennsylvania Applicants: Any person who knowingly and with intent to defraud any insurance company or other person files an application for insurance or statement of claim containing any materially false information or conceals for purposes of misleading, information concerning any fact material thereto commits a fraudulent insurance act, which is a crime and subjects such person to criminal and civil penalties.

Notice to Pennsylvania Applicants (Automobile): Any person who knowingly and with intent to injure or defraud any insurer files an application or claim containing any false, incomplete or misleading information, shall, upon conviction, be subject to imprisonment for up to seven (7) years and the payment of a fine of up to $15,000.

THE UNDERSIGNED AUTHORIZED OFFICER OF THE APPLICANT DECLARES THAT THE STATEMENTS SET FORTH HEREIN ARE TRUE, AND AFFIRMS THAT IF THE INFORMATION SUPPLIED IN THIS APPLICATION CHANGES BETWEEN THE DATE OF THIS APPLICATION AND THE EFFECTIVE DATE OF INSURANCE, THE UNDERSIGNED WILL IMMEDIATELY NOTIFY THE INSURER OF SUCH CHANGES, AND THE INSURER MAY WITHDRAW OR MODIFY ANY OUTSTANDING QUOTATIONS OR AUTHORIZATIONS OR AGREEMENT TO BIND INSURANCE. FURTHERMORE, THE UNDERSIGNED DECLARES THAT THE SIGNING OF THIS FORM DOES NOT BIND COVERAGE NOR COMMIT TO ORDERING COVERAGE.

This application is for insurance to be placed on a surplus lines basis with Hudson Excess Insurance Company.

Signature	**Date**
Print Name/Title	

Supplemental Claim Information Form

1. Full name of applicant: _____

2. Full name of claimant: _____

3. Indicate whether: Claim☐ Suit☐ Incident☐

4. Date of incident: _____ 5. Date claim was reported: _____

6. Additional defendants: _____

7. If closed:
   Total loss paid including deductible: $_____ Defense costs: _____

   Indicate whether: Court judgment☐, or Out of court settlement ☐

   Date closed: _____

8. If pending:
   Claimant's settlement demand: $_____

   Defendant's offer for settlement: $_____

   Insurer's loss reserve: $_____

   Deductible amount: $_____

   Is claim in suit? Yes☐ No☐
   If "Yes", amount asked in summons: $_____

9. Insurance carrier:_____

10. Description: (Provide enough information to allow evaluation. Use reverse side or additional sheet if required.)

A. Alleged acts, error or omission upon which Claimant bases claim:

B. Description of case and events:

C. Description of the type and extent of injury or damage allegedly sustained:

_____ _____
Signature of applicant Date