



AXIS INSURANCE

10000 Avalon Blvd. Ste. 200

Alpharetta, GA 30009

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AXIS HAS THE ABILITY TO OFFER COVERAGE ON AN OCCURRENCE FORM POLICY BASIS, ON A CLAIMS-MADE POLICY BASIS, AND WITH CLAIMS-MADE COVERAGES ATTACHED TO AN OCCURRENCE FORM POLICY.

SOLELY AS RESPECTS CLAIMS-MADE LIABILITY COVERAGES UNDER THE POLICY FOR WHICH THIS APPLICATION IS BEING SUBMITTED: THIS INSURANCE POLICY MAY CONTAIN COVERAGES THAT ARE PROVIDED ON A CLAIMS-MADE AND REPORTED BASIS AND APPLIES ONLY TO CLAIMS FIRST MADE AGAINST THE INSURED DURING THE POLICY PERIOD OR ANY APPLICABLE EXTENDED REPORTING PERIOD AND REPORTED TO THE INSURER AS SET FORTH IN THE REPORTING OF CLAIMS AND EVENTS SECTION. DEFENSE COSTS ARE INCLUDED IN THE LIMITS OF INSURANCE, AND PAYMENT THEREOF WILL ERODE, AND MAY EXHAUST, THE LIMITS OF INSURANCE.

NEW BUSINESS APPLICATION

- "Applicant," herein refers individually and collectively to all proposed insureds. All responses shall be deemed made on behalf of all proposed insureds.
- This Application and all materials submitted herewith shall be held in confidence.
- The submission of this Application does not obligate the Applicant to buy insurance nor is the Insurer obligated to sell insurance or to offer insurance upon any specific terms requested.
- If the policy applied for is issued, this Application, which shall include all Supplemental Applications and material and information submitted in connection with this Application, will be deemed attached to and will form a part of the policy.

INSTRUCTIONS

- Respond to all questions completely, leaving no blanks. Check responses when requested.
- If space is insufficient, continue responses on your letterhead.
- This Application must be completed, dated, and signed by an authorized officer of the entity identified in the section entitled "Applicant Information" below.

APPLICANT INFORMATION

1. Applicant's Name: _____

2. License Information

FDA License: _____

State Licenses:

State	License No.	Effective Date	Expiration Date

3. Is the Applicant Accredited by: ☐ CLIA ☐ AABB ☐ AATB ☐ OTHER



EXPOSURE

4. Please provide the following information of historic and projected exposures:

	Number of Donations Last 12 Months	Number of Donations Next 12 Months Projected
Paid Blood Donations		
Volunteer Blood Donations		
Autologous Donations		
Foreign Donations Purchased		
Pheresis Procedures		
Cord Blood Donations or Collection		
Other:		

	Revenues Last 12 Months	Revenues Next 12 Months Projected
Organ Donation		
Tissue Banking – Anatomical Donation		
Tissue Banking - NADO		
Other: _____		

5. Does the Applicant conduct any research? ☐ Yes ☐ No
If yes, please provide details on the research conducted and the revenue generated by research activities: _____
6. If the Applicant provides Blood or Tissue Donation services, does the Applicant obtain written informed consent from each donor or the donor's next of kin? ☐ Yes ☐ No
7. Does the Applicant contract out any of their specimen testing? ☐ Yes ☐ No
If yes, please provide details including the entity conducting the testing and the limits of insurance that entity is required to carry: _____
8. Does the Applicant conduct any specimen testing for other entities? ☐ Yes ☐ No
If yes, please detail the type of testing done and the revenue from testing for third parties: _____

BLOOD BANKING AND TISSUE BANKING

9. Does the Applicant screen donors and/or test donations for:
- a. HIV ☐ Yes ☐ No
 - b. Hepatitis B and C ☐ Yes ☐ No
 - c. HTLV ☐ Yes ☐ No
 - d. Syphilis ☐ Yes ☐ No
 - e. T. Cruzi ☐ Yes ☐ No
 - f. Other _____ ☐ Yes ☐ No



10. Does the Applicant:

- a. Have a written safety manual? ☐ Yes ☐ No
- b. Regularly schedule maintenance and calibration of all equipment? ☐ Yes ☐ No
- c. Store all specimens in accordance with FDA guidelines? ☐ Yes ☐ No

11. Does the Applicant's storage systems record storage temperatures and alert staff when storage temperatures are outside of acceptable ranges? ☐ Yes ☐ No

If yes, please indicate who is responsible for receiving alerts:

12. Does the Applicant's storage facility have systems in place for safe storage during power outages?

☐ Yes ☐ No

13. If the Applicant is a Tissue Bank, does it adhere to the FDA's Current Good Tissue Practices?

☐ Yes ☐ No

If no, please explain: _____

ORGAN PROCUREMENT ORGANIZATIONS

14. What is your designated Service Area: _____

15. Is the Applicant in compliance with all of CMS' Conditions for Coverage? ☐ Yes ☐ No

16. Does the Applicant Screen Donors for:

- a. HIV ☐ Yes ☐ No
- b. Hepatitis B and C ☐ Yes ☐ No
- c. CMV ☐ Yes ☐ No
- d. RBV ☐ Yes ☐ No
- e. Syphilis ☐ Yes ☐ No
- f. Toxoplasma Gondii ☐ Yes ☐ No
- g. T. Cruzi ☐ Yes ☐ No
- h. Other _____ ☐ Yes ☐ No

RISK MANAGEMENT

17. Does the Applicant have a formal Risk Management/Quality Assurance program? ☐ Yes ☐ No

18. Does the Risk Management/Quality Assurance Program:

- a. Have a procedure to identify and document all specimens? ☐ Yes ☐ No
- b. Have a procedure to document chain of custody from the donor to the recipient? ☐ Yes ☐ No



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SUPPLEMENTAL APPLICATION

- c. Have a procedure for ensuring safe handling of all specimens? ☐ Yes ☐ No
- d. Have audit practices to ensure that written policies and procedures are implemented? ☐ Yes ☐ No

19. Please provide the name and qualifications of the Applicant's risk manager:

LOSS INFORMATION

20. Has the Applicant had any adverse events, recalls, warnings, and or withdrawals related to its donations or products in the last five (5) years? ☐ Yes ☐ No

If yes, please provide details on the event and the corrective action initiated in response:

21. Has a Governmental Entity or Accrediting Organization conducted an inspection of the Applicant's facility? ☐ Yes ☐ No

If yes:

- a. Please indicate the inspecting entity and the date of the last inspection: _____
- b. Were any deficiencies identified in the course of the inspection? ☐ Yes ☐ No

If yes, please provide details: _____

REPRESENTATIONS AND SIGNATURE

By signing this document, the undersigned authorized representative of the Applicant represents on behalf of all persons and entities proposed for coverage, after inquiry, that to the best of their knowledge:

22. The statements and answers given in, and all materials submitted with this Application are true, accurate and complete.
23. No facts or information material to the risk proposed for insurance have been misstated or concealed.
24. These representations are a material inducement to the Insurer to provide a proposal for insurance.
25. Any policy the Insurer issues will be issued in reliance upon these representations.
26. The Applicant will report to the Insurer immediately in writing any material change in the Applicant's activities, products and services.
27. The Applicant will report to the Insurer immediately in writing any material changes to the answers provided in this Application which occur or are discovered between the date of this Application and the effective date of the policy for which coverage is sought by submission this Application.
28. The Insurer reserves the right, upon receipt of any such notice, to modify or withdraw any proposal for insurance the Insurer has offered.

WARNING

PLEASE REVIEW THE STATE FRAUD STATEMENT CONTAINED AT THE END OF THIS APPLICATION APPLICABLE TO THE STATE IN WHICH THE APPLICANT RESIDES.

Any person who, with intent to defraud or knowingly facilitates a fraud against the insurer, submits an application or files a claim containing a false or deceptive statement may be guilty of insurance fraud.



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This Application must be signed by the Applicant's Chief Executive Officer, Chief Financial Officer, Chief Operations Officer or General Counsel, or their functional equivalent, unless the Insurer instructs the Applicant otherwise.

_____	_____
Name	Name (signature)
_____	_____
Title	Date

Produced By:

Agent: _____ Agency: _____

Agency Taxpayer ID or SS No.: _____ Agent License No.: _____

Address: _____

City: _____ State: _____ Zip: _____



STATE FRAUD STATEMENT

ALABAMA

Any person who knowingly presents a false or fraudulent claim for payment of a loss or benefit or who knowingly presents false information in an application for insurance is guilty of a crime and may be subject to restitution fines or confinement in prison or any combination thereof.

ARKANSAS

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.

CALIFORNIA

For your protection, California law requires the following warning 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.

COLORADO

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 claimant with regard to a settlement or award payable from insurance proceeds shall be reported to the Colorado division of insurance within the department of regulatory agencies.

DISTRICT OF COLUMBIA

Warning: It is a crime to provide false or misleading information to an insurer for the purpose of defrauding the insurer or any other person. Penalties include imprisonment and/or fines. In addition, an insurer may deny insurance benefits if false information materially related to a claim was provided by the Applicant.

FLORIDA

Any person who knowingly and with intent to injure, defraud, or deceive any insurer files a statement of claim or an application containing any false, incomplete or misleading information is guilty of a felony of the third degree.

KANSAS

A "fraudulent insurance act" means 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 electronic, electronic impulse, facsimile, magnetic, oral, or telephonic communication or 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.

KENTUCKY

Any person who knowingly and with intent to defraud any insurance company or other person files an application for insurance 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.

LOUISIANA

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.

MAINE

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 or a denial of insurance benefits.

MARYLAND

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.

NEW JERSEY

Any person who includes any false or misleading information on an application for an insurance policy is subject to criminal and civil penalties.

NEW MEXICO

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 civil fines and criminal penalties.

NEW YORK

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 five thousand dollars and the stated value of the claim for each such violation.

OHIO

Any person who, with intent to defraud or knowing that he is facilitating a fraud against an insurer, submits an application or files a claim containing a false or deceptive statement is guilty of insurance fraud.

OKLAHOMA

WARNING: Any person who knowingly, and with intent to injure, defraud or deceive any insurer, makes any claim for proceeds of an insurance policy containing any false, incomplete or misleading information is guilty of a felony.

OREGON

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

In order for us to deny a claim on the basis of misstatements, misrepresentations, omissions or concealments on your part, we must show that:

- A. The misinformation is material to the content of the policy;
- B. We relied upon the misinformation; and
- C. The information was either:
 - 1. Material to the risk assumed by us; or



2. Provided fraudulently.

For remedies other than the denial of a claim, misstatements, misrepresentations, omissions or concealments on your part must either be fraudulent or material to our interests.

With regard to fire insurance, in order to trigger the right to remedy, material misrepresentations must be willful or intentional.

Misstatements, misrepresentations, omissions or concealments on your part are not fraudulent unless they are made with the intent to knowingly defraud.

PENNSYLVANIA

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 subjects such person to criminal and civil penalties.

PUERTO RICO

Any person who knowingly and with the intention of defrauding presents false information in an insurance application, or presents, helps, or causes the presentation of a fraudulent claim for the payment of a loss or any other benefit, or presents more than one claim for the same damage or loss, shall incur a felony and, upon conviction, shall be sanctioned for each violation with the penalty of a fine of not less than five thousand dollars (\$5,000) and not more than ten thousand dollars (\$10,000), or a fixed term of imprisonment for three (3) years, or both penalties. Should aggravating circumstances be present, the penalty thus established may be increased to a maximum of five (5) years, if extenuating circumstances are present, it may be reduced to a minimum of two (2) years.

RHODE ISLAND

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.

TENNESSEE

It is a crime to knowingly provide false, incomplete or misleading information to an insurance company for the purpose of defrauding the company. Penalties include imprisonment, fines and denial of insurance benefits.

VERMONT

Any person who knowingly presents a false statement in an application for insurance may be guilty of a criminal offense and subject to penalties under state law.

VIRGINIA

It is a crime to knowingly provide false, incomplete or misleading information to an insurance company for the purpose of defrauding the company. Penalties include imprisonment, fines and denial of insurance benefits.

WASHINGTON

It is a crime to knowingly provide false, incomplete or misleading information to an insurance company for the purpose of defrauding the company. Penalties include imprisonment, fines and denial of insurance benefits.

WEST VIRGINIA

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.