BIOPRO INSURANCE PROGRAM

New Business Application

This is an application for a Claims-Made Policy.

LIFE SCIENCES LIABILITY

APPLICANT'S INSTRUCTIONS

- Please attach a copy of your most recent financial statements, if you are privately held.
- Attach 5 years of insurance carrier loss runs, valued within the last 60 days.
- Do not leave any space blank. If a question or section is not applicable, please answer "N/A." For any "**Yes**" answers, please provide an explanation on the page titled "Explanations."

Throughout this application, "you" refers to the person or organization seeking coverage.

What insurance coverage and limit of liability are you seeking?

Coverage	Limit of Liability	Deductible	Retroactive Date
General Liability, including Products-Completed Operations Liability	$	$	
Products-Completed Operations Liability only	$	$	
Human Clinical Trials Liability only	$	$	

SECTION A – GENERAL INFORMATION

1. Applicant Information

APPLICANT NAME:

STREET ADDRESS	CITY/STATE	ZIP CODE	PHONE NUMBER	DATE ESTABLISHED

MAILING ADDRESS	WEB ADDRESS

APPLICANT TYPE

☐ Individual ☐ Corporation ☐ Partnership ☐ Joint Venture ☐ Limited Liability Company ☐ Other (Specify):

Have you ever operated under a different name? YES ☐ NO ☐

If yes, provide details.

Do you have a parent company? If yes, provide details below. YES ☐ NO ☐

COMPANY NAME:

STREET ADDRESS	CITY/STATE	ZIP CODE

2. Please briefly describe your products and operations:

3. Requested Additional Insureds

Entity Name	Your % Ownership	Relationship to Applicant

4. List companies or assets you acquired (A) or sold (S) within the past five years

Entity Name	A	S	Date Acquired/Sold	Description
	☐	☐		
	☐	☐		

SECTION B – PRODUCTS AND OPERATIONS

Clinical Trial Applicants: **SKIP** to Section E on Page 6

Products and Operations

1. Provide the following information for those products, goods and/or services the Applicant wants coverage for. Only those products, goods and services listed below will be considered for coverage.

Products and Services	Applicant Acts as a(n)					No. of Years	% of Gross Receipts	Products and Goods sold to:				
	M	W	R	I	MR			M	W	R	I	MR
	☐	☐	☐	☐	☐			☐	☐	☐	☐	☐
	☐	☐	☐	☐	☐			☐	☐	☐	☐	☐
	☐	☐	☐	☐	☐			☐	☐	☐	☐	☐
	☐	☐	☐	☐	☐			☐	☐	☐	☐	☐

M: Manufacturer **W:** Wholesaler **R:** Retailer **I:** Importer

MR: Manufacturer's rep. **C:** Consumer direct **O:** Other (describe):

If you described yourself as a **Distributor** or **Manufacturer's Rep** in the table above, skip to **Section D – Distributors and Manufacturer's Representatives** on Page **5**

2. Annual Sales

	US/Canada Sales	Rest of World Sales	Total Sales
Upcoming Year			
Last Year			
2 Years Prior			
3 Years Prior			

3. Have you ever filed for bankruptcy? YES ☐ NO ☐

If yes, please provide details.

4. List your 5 best-selling products and estimated sales for each during the upcoming policy period:

Product Name	Estimated Sales
	$
	$
	$
	$
	$

5. Do you manufacture your own products? YES ☐ NO ☐

6. Do others manufacture your products? YES ☐ NO ☐
If yes, please provide the following information:

Contract Manufacturer Name	Product Name(s)	Estimated Annual Sales
		$
		$
		$

a. Do you collect Certificates of Insurance from each of your contract manufacturers? YES ☐ NO ☐

b. Do you regularly conduct Good Manufacturing Practices ("GMP") or similar production facility audits of your contractors' operations? YES ☐ NO ☐

If no, please describe how you verify contractor compliance with GMP standards:

7. Do you manufacture products that are components of another's finished products? YES ☐ NO ☐

8. Do you manufacture finished products for others to sell under their label? YES ☐ NO ☐

9. Are any of your products implanted into the human body for more than 30 days? YES ☐ NO ☐
If yes, list each product and the estimated sales volume and number of units sold for each product during the upcoming policy period.

Product Name/Description	Annual Sales	Annual Units Sold

10. Are any products or component parts sourced from foreign suppliers or manufacturers? YES ☐ NO ☐
If yes, please provide the following information:

Product/Component Name	Supplier/Manufacturer Name	Country of Origin

11. Do you install, customize, service or repair your products? YES ☐ NO ☐

12. Do you install, customize, service or repair products manufactured by others? YES ☐ NO ☐
If yes, please provide the following information:

Product Name	Product Manufacturer Name	Services You Provide for these products	Annual revenues from this work

13. Do others install, customize, service or repair your products? YES ☐ NO ☐
If yes, please answer the questions below:

a. Do you require these firms to carry liability insurance? YES ☐ NO ☐

b. Do you provide these firms with written instructions? YES ☐ NO ☐

c. Do you provide these firms with formal training? YES ☐ NO ☐

14. List any new products you expect to start selling in the next 12 months and the estimated sales for each:

Product	Estimated Sales

15. Have any of your products been discontinued in the past five years? YES ☐ NO ☐
If yes, please list each product and the reason it was discontinued.

Product	Reason Discontinued

SECTION C – QUALITY AND REGULATORY INFORMATION

1. Do you have a full-time quality control manager who reports to senior management? YES ☐ NO ☐

2. Do you utilize formal quality assurance/quality control systems and procedures? YES ☐ NO ☐

3. Are you registered with the FDA? YES ☐ NO ☐

a. If yes, when was your last FDA inspection? Date ☐

b. Was an FDA Form 483 issued? If yes, please attach a copy and your written response thereto. ☐

4. Has the FDA issued a Warning Letter to you in the last five years? YES ☐ NO ☐

If yes, please provide a copy of the Warning Letter and your written response.

5. Have you or a third-party performed a Good Manufacturing Practices ("GMP") or similar production facility audit of your operations within the last 12 months? If yes, please provide a copy of your most recent GMP audit results. YES ☐ NO ☐

6. Do you have a written plan for product recalls? YES ☐ NO ☐

7. Have any of your products been recalled, withdrawn or removed from the market for any reason? YES ☐ NO ☐

If yes, please provide details.

8. Do you advertise your product directly to consumers/patients? YES ☐ NO ☐

   If yes, indicate the formats in which you advertise (i.e. television, print media, etc.)

9. Do any of your products require a significant safety warning? YES ☐ NO ☐
   If yes, please attach copies of all significant safety warnings.

SECTION D – DISTRIBUTORS AND MANUFACTURERS REPRESENTATIVE

Distributors and Manufacturer Representatives

Projected Annual Product Sales

Manufacturer Represented	Manufacturer's Country of Domicile	Annual Sales US and Canada	Annual Sales Rest of World

Projected Annual Service Revenue

	Manufacturer Name and Country of Domicile	Annual Revenues US and Canada	Annual Revenues Rest of World
Leasing			
Installation			
Service/Repair/Maintenance			

1. Do you distribute products under your name or label? YES ☐ NO ☐
2. If you contract the manufacturing of your product to others, do you have a formal written agreement with your subcontractors? YES ☐ NO ☐
3. Are you a manufacturer's representative? If yes, attach the written agreement between you and the manufacturer. YES ☐ NO ☐
4. Do you obtain Certificates of Insurance from all manufacturers/suppliers evidencing Product Liability insurance? YES ☐ NO ☐

   Are you included as an Additional Insured-Vendor under each manufacturer's/supplier's Product Liability insurance? YES ☐ NO ☐

   What are the minimum limits of insurance required?

5. Percentage of equipment sold or leased/rented which is physician prescribed:
6. Do you maintain the following records:
   a. When and where your product was manufactured? YES ☐ NO ☐
   b. To whom your product was sold and the date of sale? YES ☐ NO ☐
   c. Who manufactured the product? YES ☐ NO ☐
   d. Changes in design? YES ☐ NO ☐
   e. Changes in advertising material? YES ☐ NO ☐
   f. Product user complaints? YES ☐ NO ☐

   How long do you maintain these records?

SECTION E – HUMAN CLINICAL TRIALS

Please list clinical trials that are ongoing or anticipated during the policy period. Attach a copy of the Protocol and Informed Consent Form for each clinical trial.

Study Name & Protocol Number	Trial Phase	Product Name	Total Number of Subjects	Number of subjects enrolled during policy period	Number of trial sites	Country (ies) where trial will take place

1. What is the total number of human subjects enrolled in your clinical trials in the last 3 years?

2. Have any clinical trials involving your product(s) ever been suspended or terminated for safety reasons? YES ☐ NO ☐

   If yes, please provide details.

3. Have any subjects in your clinical trials ever experienced a serious adverse event? YES ☐ NO ☐

   If yes, please provide details.

4. Are you using a Contract/Clinical Research Organization ("CRO") for any of your studies? YES ☐ NO ☐

5. Are you using properly registered Institutional Review Boards (IRBs)? YES ☐ NO ☐

6. Have any of your CROs, IRBs, or clinical investigators ever been cited for regulatory violations? YES ☐ NO ☐

7. Do you ever act as both trial sponsor and clinical investigator? YES ☐ NO ☐

8. Do you ever provide products or materials for use in investigator-sponsored clinical trials? YES ☐ NO ☐

   If yes, please provide details.

9. Are any of your investigational/unapproved products provided to seriously ill individuals who are not candidates for clinical trials under expanded access, compassionate use, right-to-try or similar programs? YES ☐ NO ☐

   If yes, please provide details.

SECTION F – PHYSICAL LOCATION
(Complete this section if GL coverage is desired)

1. How is access to your premises controlled?

   ◯ a. Access is not allowed without a card or employee escort

   ◯ b. Front desk registration only

   ◯ c. Front desk registration only

2. Do you keep hazardous substances on site? YES ☐ NO ☐
   If yes:

a. How many gallons are kept on site?

b. How are hazardous substances kept on site (check all that apply)?

- ☐ Outdoor storage
- ☐ indoor, restricted-access area, in approved containers
- ☐ Just in time supply
- ☐ indoor, restricted-access area, unapproved containers
- ☐ Other (please explain)

c. Are you in compliance with hazardous materials regulations? YES ☐ NO ☐

3. What is your highest biohazard lab rating?

4. Does your site include a clean room? YES ☐ NO ☐

   If so, what is its current rating?

5. Do you house animals or have an animal facility? YES ☐ NO ☐

6. Do you have an Enterprise Risk/Safety Program? YES ☐ NO ☐

   If yes, what are your main areas of focus?

7. How often are your risk management programs and SOPs audited?

8. Do you have any risk management programs or Standard Operating Procedures audited by third-parties? YES ☐ NO ☐

   If so, how often are these audits conducted?

9. Do you require all new employees to participate in training that instructs them on all company policies and procedures? YES ☐ NO ☐

10. Do you require Certificates of Insurance from all of your contractors, sub-contractors and suppliers? YES ☐ NO ☐

    If so, what limits and terms do you require?

11. Do you have a formalized information security policy that dictates the protocols that control access to use all critical data, process or information systems for all authorized users, including business partners and third parties? YES ☐ NO ☐

12. Do you have an information security officer? YES ☐ NO ☐

13. Do you have a formalized privacy policy in place? YES ☐ NO ☐

14. Do you have a crisis management team in place? YES ☐ NO ☐

SECTION G – INSURANCE HISTORY AND CLAIM INFORMATION

1. For each type of coverage you are seeking, provide your insurance history for the past 5 years:

Coverage Type	Effective Dates	Insurance Company	Limit of Insurance	Deductible or SIR	Premium	Retroactive Date

*** Please attach currently dated insurance company loss runs for the past 5 years.**

2. Has any insurance company cancelled or refused to renew your insurance? YES ☐ NO ☐

   If yes, please explain.

3. Are there any claims that have not yet been reported? YES ☐ NO ☐

   If yes, please explain.

4. Are there any acts, facts, incidents, circumstances or situations which could result in claims against you under the insurance coverage requested in this application? YES ☐ NO ☐

   If yes, please explain.

5. How many adverse events have been reported to you and/or the FDA concerning your products in the last 5 years? Please provide details.

6. How many customer complaints have you received concerning your products in the last 5 years? Please provide details.

7. Is any person or organization proposed for this insurance aware of any fact, incident, circumstance, situation, condition, defect or suspected defect which may result in a claim, such that would fall under the proposed insurance? YES ☐ NO ☐

   If yes, please provide details.

8. Has any claim been made against any person or organization proposed for this insurance during the last five (5) years? YES ☐ NO ☐

   If yes, please provide five (5) year loss history for all claims, including any predecessor. Attach a description of any loss greater than $10,000.

Year	No. of Claims	Total Amounts Paid	Amounts Reserved	Total Incurred	Date of Loss Info.

FRAUD WARNING

NOTICE TO ALABAMA, ALASKA, ARIZONA, ARKANSAS, CALIFORNIA, CONNECTICUT, DELAWARE, GEORGIA, IDAHO, ILLINOIS, INDIANA, IOWA, KANSAS, MARYLAND, MASSACHUSETTS, MICHIGAN, MINNESOTA, MISSISSIPPI, MISSOURI, MONTANA, NEBRASKA, NEVADA, NEW HAMPSHIRE, NORTH CAROLINA, NORTH DAKOTA, OREGON, RHODE ISLAND, SOUTH CAROLINA, SOUTH DAKOTA, TEXAS, UTAH, VERMONT, WASHINGTON, WEST VIRGINIA, WISCONSIN, AND WYOMING APPLICANTS: In some states, 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 in many states.

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 policy holder 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 APPLICANTS: 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.

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 HAWAII APPLICANTS: For your protection, Hawaii law requires you to be informed that presenting a fraudulent claim for payment of a loss or benefit is a crime punishable by fines or imprisonment, or both.

NOTICE TO KENTUCKY APPLICANTS: 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.

NOTICE TO 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 MAINE APPLICANTS: 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 denial of insurance benefits.

NOTICE TO NEW JERSEY APPLICANTS: Any person who includes any false or misleading information on an application for an insurance policy is subject to criminal and civil penalties.

NOTICE TO NEW MEXICO 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 civil fines and criminal penalties.

NOTICE TO NEW YORK APPLICANTS: Any person who knowingly and with intent to defraud an 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 OHIO APPLICANTS: Any person who, with intent to defraud or knowing that he/she 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.

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

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 a 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 the person to criminal and civil penalties.

NOTICE TO TENNESSEE APPLICANTS: 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.

NOTICE TO VIRGINIA APPLICANTS: 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.

The Applicant acknowledges that the answers provided herein are based on a reasonable inquiry and/or investigation. The Applicant warrants that the above statements and particulars together with any attached or appended documents are true and complete and do not misrepresent, misstate or omit any material facts.

The Applicant agrees to notify us of any material changes in the answers to the questions on this questionnaire which may arise prior to the effective date of any policy issued pursuant to this questionnaire and the Applicant understands that any outstanding quotations may be modified or withdrawn based upon such changes at our sole discretion. Completion of this form does not bind coverage. Applicant's acceptance of the company's quotation is required prior to binding coverage and policy issuance. All written statements and materials furnished to the company in conjunction with this application are hereby incorporated by reference into this application and made a part of this application.

APPLICANT NAME	TITLE	FEIN #:
APPLICANT'S SIGNATURE	DATE	
AGENT / BROKER NAME		