JAMES RIVER GROUP	James River Insurance Company	**Life Sciences General Application** **ALLIED HEALTHCARE Division**

APPLICANT'S INSTRUCTIONS:

1. Answer all questions completely. Please attach extra sheets as required. Incomplete or illegible applications may be discarded.
2. Application must be signed and dated by the owner, partner, or officer not earlier than 45 days before the proposed effective date of coverage.
3. Please read the statements at the end of this application carefully. Thank you!

LIFE SCIENCES GENERAL APPLICATION

PLEASE ATTACH THE FOLLOWING:

- **Financial Statement (most recent fiscal year)**
- **Copy of Current Facility License**
- **Copy of Current State Inspection**
- **5 Year loss runs currently valued**
- **Sample contract between you and clinical investigator (if applicable)**
- **All Advertisements, brochures, literature**
- **Informed consent document (if applicable)**
- **List of all medical devices**
- **Copy of all product warranties**

I. APPLICANT INFORMATION

Applicant Name: _____

Mailing Address: _____

County: _____ Phone Number: _____

Years in business under current management: _____ Date Established: _____

Website: _____ Inspection Contact: _____

Type of Enterprise: Corporation ☐ Individual ☐ Partnership ☐ Non-Profit ☐
For Profit ☐ Joint Venture ☐ Other ☐

Revenue/Operating Budget: _____

Estimate for the Next 12 Months $ _____ Number of Employees _____
Actual for the Past 12 Months $ _____
Estimated Payroll for the Next 12 Months $ _____

Additional Offices: _____

Name of Parent Company: _____

Has applicant operated under a different name? Yes ☐ No ☐ If "Yes", please explain.
_____

II. CLINICAL TRIAL SECTION

FULL DESCRIPTION OF SERVICES RENDERED:

_____

_____

_____

Percentage of foreign professional services and names of countries involved: _____

Please indicate the specific phase of clinical testing for which coverage is sought:

_____

Please describe this phase: _____

Will this phase be and have all prior phases been performed in accordance with an FDA approved protocol? Yes ☐ No ☐
If no, please explain: _____

Please provide the Investigational New Drug (IND) number: _____

Will any healthcare services be provided in conjunction with this clinical trial? Yes ☐ No ☐
If "Yes", describe the services and provider:

_____

_____

What are the average annual expenditures for medical treatments for side effects sustained by clinical trial participants over the last three years? _____

Number of completed human clinical trials in the past three years: _____

Number of subjects enrolled: _____

Is the clinical investigator an employee of your entity? Yes ☐ No ☐

Is the clinical investigator an employee of the test site facility? Yes ☐ No ☐

Have any clinical trials been suspended or discontinued due to safety reasons? Yes ☐ No ☐
If "Yes", please explain:

_____

_____

Have any of the applicant's Clinical Investigators been cited for regulatory violations?
Yes ☐ No ☐

If "Yes", please explain:

_____

_____

Has applicant had any evidence of serious regulatory non-compliance or fraud by applicants Clinical Investigators or their staff in the past five years?
Yes ☐ No ☐

If "Yes", please explain:

_____

_____

How many clinical trial "For Cause Audits" were conducted by the applicant, FDA or Office for Human Research Protection (OHRP) in the last five years? _____

Have you ever been inspected, surveyed or audited by the FDA, the Center for Drug Evaluation and Research, or the Center for Biologics Evaluation and Research? Yes ☐ No ☐

Have you ever been subject to any inquiry or investigation by any federal, state or local agency concerning your professional services? Yes ☐ No ☐

Do you operate in compliance with the FDA's Good Clinical Practice Guidelines? Yes ☐ No ☐

Have you ever been cited for any non-compliance of Good Clinical Practices or any federal, state or local law, ordinance, directive or regulation? Yes ☐ No ☐

Is the applicant in compliance with applicable state regulations regarding human clinical trials? Yes ☐ No ☐

Does applicant require Clinical Investigators to test participants on their understanding of the informed consent document(s)? Yes ☐ No ☐

Please describe the results of any previous related trials:

_____
_____
_____
_____

Please describe in complete detail any adverse results from previously related trials including animal studies and/or toxicity studies:

_____
_____
_____
_____

List all products that will be in the human clinical trial phase during the next 12 months.

[Also provide copy of the protocol(s), including informed consent document(s).]

Product	Description	# of patients	Trial Phase	Trial Length	Trial Location

Please identify the age and sex of the test subjects: _____

Please detail the method in which test subjects will be recruited: _____

Will test subjects be required to sign an informed consent document? Yes ☐ No ☐
If "Yes", please attach.

How will the trial be conducted and by whom? _____

Please attach a detailed explanation:

_____

_____

Please detail any and all products involved with this trial?

_____

_____

What are the known and/or possible side effects? _____

How are test subjects notified of these side effects? _____

How will the trial be funded? _____

Where will the trial be performed and what type of institution is the site?

☐ Non-Profit Testing Institute ☐ Clinical research Center
☐ Private Facility ☐ Other (please describe)

Will an Institutional Review Board oversee the trials? Yes ☐ No ☐

Are you a member of this Board? Yes ☐ No ☐

Please list the number of employed professionals or independent contractors: (state none if applicable)

	Employee	**Independent Contractor**	**Total**
RN/LPN			
Lab Technician			
Clinical Investigator			
Clinical Research Assoc.			
Physician			
Medical Monitor			
Engineer			
Biostatistician			
Data Entry			
Legal Counsel			
Other			

Do you perform any environmental testing or consulting? Yes ☐ No ☐
If "Yes", please attach a detailed explanation:

_____

_____

Please indicate testing that has been performed on specified products in the past 12 months and that is anticipated during the next 12 months:

	Last 12 Months	Next 12 Months
Hormones & Steroids		
Vaccines		
Injectables		
Prescription Products		
Over the Counter		
Weight Loss Aids		
Vitamins		
Food Supplements		
Novel Drugs		
General Off-Patient		
Products, other than above		
Instruments (x-diagnostic)		
Cosmetic, Health, Beauty Aids		
Surgical Equipment		
Diagnostic Instruments		
Therapeutic Devices		
Life Support		
Other		

III. PRODUCTS AND DEVICES SECTION

Do you manufacture or sell any products? Yes ☐ No ☐

If "Yes", please attach a detailed description of any current or future products that you anticipate:

_____

_____

Please list the name and proposed use or function of the product being tested or manufactured:

Products, Devices and Services (please list class for devices also)	Applicant Acts as a/an: M | W | R | I |MR	No. of years	% of gross sales	Does applicant: Install? | Repair or service?	Products sold to: M | W | R | I | MR	Projected # of annual users:	Annual Revenue

M - manufacturer W - wholesaler R - retailer I - importer MR - manufacturers rep.
C - consumer- direct O - other (describe) _____

Are you aware of any other approved or suggested uses or functions of the product being tested or manufactured? Yes ☐ No ☐

If "Yes", please attach a detailed explanation:

_____

_____

Do you have any knowledge that this product or any of its components might effect any immune system reactions? Yes ☐ No ☐
If yes, please attach a detailed explanation:

_____

_____

Please list the name of the product manufacturer (if other than yourself): _____

With respect to those products for which coverage is desired:

Who designs your products? _____
(Please attach their professional qualifications.)

Do others design, engineer, manufacture, assemble or package any of the products or components thereof for which coverage is desired under your name or label? Yes ☐ No ☐

Are designs reviewed, tested and verified by others? Yes ☐ No ☐

Do you maintain records of changes in designs, advertisements and sales brochures?

Yes ☐ No ☐

Are all instructions, operating materials, advertisements and warranties periodically reviewed by Legal Counsel to avoid misunderstanding relative to product safety, intended use, product performance, quality, fitness, or durability? Yes ☐ No ☐

Do the warranties you issue in connection with your products contain time constraints within which detected substandard performance must be reported to you? Yes ☐ No ☐

Please attach a copy of all warrantees.

Are your products designed, tested, labeled and manufactured to meet or exceed all applicable government and industry standards? Yes ☐ No ☐

To what extent do the levels of performance designed into your products exceed the levels of performance specified in your literature? _____

Are any of your products subject to registration/regulation/review by any government agency? Yes ☐ No ☐

If "Yes", please explain: _____

Do you import component parts used in any of your listed products? Yes ☐ No ☐

Is the Applicant considered a "Covered Entity" under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule? Yes ☐ No ☐

If "Yes", have compliance procedures been implemented? Yes ☐ No ☐

When did the FDA conduct its most recent 0n-site establishment inspection? Month ___Year____
Was a 483 issued? Yes ☐ No ☐
If "Yes", attach 483 and your response.

Have any medical device adverse event reports (MDR's) been filed in the last 12 months? Yes ☐ No ☐

If "Yes", please attach copies.

Do you have a specific program to withdraw known or suspected defectively designed products from the market? Yes ☐ No ☐

Have you ever recalled or are you considering recalling any known or suspected defectively designed products from the market? Yes ☐ No ☐
If "Yes", please specify which products: _____

What products have you ceased manufacturing in the past ten years? _____

Have any products been acquired by merger or acquisition? Yes ☐ No ☐
If "Yes", please explain: _____

Can the date of manufacture by each product be identified by the factory numbers stamped on it? Yes ☐ No ☐

If you are a distributor and do not actually manufacture the products you sell, does your manufacturer(s) provide you with vendors liability coverage? Yes ☐ No ☐

IV. PROFESSIONAL SERVICES *(percentages)**:***

Clinical Trials Management		Product Recall/Withdrawal	
Site Phase 1 Services		Equipment Maintenance/Sterilization	
Clinical Trials Packaging		Quality Systems & Regulatory Compliance	
CLIA Certified Lab Services		Sales & Marketing	
Communications & Publications		Software Development or Product Design	
Health Management, Economic, & Policy Research		Manuf/Distribution/Packaging/Mixing/ Labeling	
Information Services/Databases		Pharmacoviligence/Safety Surveillance	
Institutional Review Board		Other *(please explain)*	
Pre-clinical Development			
Details:			

V. CURRENT INSURANCE:

Has applicant had previous insurance for this enterprise? Yes ☐ No ☐
If "Yes", complete the following:

Products Liability		Clinical Testing Liability	
Current Carrier		Current Carrier	
Policy Term		Policy Term	
Premium		Premium	
Deductible/SIR		Deductible/SIR	
Primary & Excess Limits		Primary & Excess Limits	
Retro Date		Retro Date	

VI. REQUESTED COVERAGE:

Coverage	Limits Requested	Deductible/SIR
Premise & Operations Liability		
Products & Completed Operations		
Professional Liability (Errors and Omissions)		
Other		

If excess coverage is being requested, please provide underlying policy terms and conditions.

VII. CLAIM HISTORY:

During the past five (5) years, have any claims been presented to your current or prior insurance carrier or to you? Yes ☐ No ☐ If "Yes", complete the following: (If more than two (2) claims, attach a separate sheet describing the losses.)	
Date of loss:	Is Claim Open? Yes ☐ No ☐
Current reserve or amount paid:	
Description of loss:	
Date of loss:	Is Claim Open? Yes ☐ No ☐
Current reserve or amount paid:	
Description of loss:	
Has any applicant, or any other person for whom insurance is being requested, aware of any circumstances, which may result in a claim?	Yes ☐ No ☐
Has any applicant ever been cancelled or non-renewed in the past five (5) years?	Yes ☐ No ☐
Has any license or accreditation ever been suspended, denied or revoked?	Yes ☐ No ☐
Of what professional association(s) is Insured a member in good standing?	

VIII. PREMISES INFORMATION:

Indicate which of the following applies to applicant's premises: access is not allowed without card and/or authorized employee, front desk registration only, or no restricted access.	
Indicate which of the following applies: hazardous substances are kept outdoors or in a cut-off within approved containers, just in time supply levels, cut-off area with unapproved containers.	
Indicate how many gallons of hazardous substances are kept on site?	
Biohazard Lab Rating if applicable?	
If applicable is the applicant in compliance with 49 CFR 172.702PART 172--Hazardous Materials Table, Special Provisions, Hazardous Materials Communications, Emergency Response Information, And Training Requirements?	
Has applicant ever hired key employees from direct competitors?	
Does applicant ever do direct product comparisons against competitor products?	

NOTICE TO APPLICANT: The coverage applied for is solely as stated in the policy. If policy is issued on a "CLAIMS MADE" or "CLAIMS MADE AND REPORTED" basis, it provides coverage only for those claims that are first made against the insured during the policy period unless the extended reporting period option is exercised in accordance with the terms of the policy. If issued on an "OCCURRENCE" basis, the policy provides coverage only for those occurrences that take place during the policy period.

The Insurer will rely upon this application and all such attachments in issuing the policy. If the information in this application or any attachment materially changes between the date this application is signed and the effective date of the policy, the Applicant will promptly notify the Insurer, who may modify or withdraw any outstanding quotation or agreement to bind coverage.

In 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.

In all other states: It is a crime for any person to knowingly provide or facilitate in providing any false, incomplete, or misleading information to an insurance company. Penalties may include fines, imprisonment and denial of insurance benefits.

WARRANTY: I warrant to the Insurer, that I understand and accept the notice stated above and that the information contained herein is true and that it shall be the basis of the policy of insurance and deemed incorporated therein, should the Insurer evidence its acceptance of this application by issuance of a policy. I authorize the release of claim information from any prior insurer to James River Insurance Company, 7130 Glen Forest Drive, Richmond, VA 23226.

Applicant's Name:	Signature
Title:	Date:

