	James River Insurance Company and its Subsidiaries 6641 West Broad Street, Suite 300 Richmond, VA 23230	**Life Sciences General Application** **LIFE SCIENCES Division** Email to LS@jamesriverins.com

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 90 days before the proposed effective date of coverage.
3. Please read the statements at the end of this application carefully. Thank you!

Additional information required for this submission:

- Financial statement *(most recent fiscal year)*
- Copy of current facility license *(if applicable)*
- Copy of current state inspection *(if applicable)*
- 5 year loss runs currently valued
- All advertisements, brochures, literature
- Sample contract between you and clinical investigator *(if applicable)*
- Informed consent document *(if applicable)*
- List of all medical devices
- Copy of all product warranties

SECTION I – GENERAL INFORMATION

Applicant name:

DBA:

Address:

City: State: Zip:

Phone: Ext: Website:

Years in business under current management: Date established:

Inspection contact name and information:

Type of enterprise: ☐ Corporation ☐ Individual ☐ Partnership ☐ Proprietorship ☐ LLC ☐ Non-profit ☐ For profit ☐ Joint venture ☐ Government entity ☐ Other:

Description of operations:

List of subsidiaries and their operations:

List any additional offices and provide locations:

Have any of the principals engaged in this or similar enterprises under a different name? ☐ Yes ☐ No
If "Yes", please list entity and operations:

Provide business financial information for the last five (5) years and estimates for the next year:

Year	Domestic sales	Foreign sales	Payroll	# of employees
Next year				
Last year				
2nd year prior				
3rd year prior				
4th year prior				
5th year prior				

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SECTION II – CLINICAL TRIAL SECTION

1. Provide a full description of services provided and detail the applicant's role in the clinical trial *(e.g., trial sponsor, research site, product manufacturer)*:

2. Provide the percentage of foreign professional services and names of countries involved: %

3. Indicate the specific phase of clinical testing for which coverage is sought:

4. Is applicant aware of any regulatory non-compliance or fraud by applicant's clinical investigators or their staff in the past five (5) years? ☐ Yes ☐ No
   If "Yes", please explain:

5. How many clinical trials "For Cause Audits" were conducted by the applicant, FDA, or Office for Human Research Protection (OHRP) in the last five (5) years?

6. Has applicant 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

7. Does applicant operate in compliance with the FDA's Good Clinical Practice Guidelines? ☐ Yes ☐ No

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

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

10. Is 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

11. Does applicant require clinical investigators to test participants on their understanding of the informed consent document(s)? ☐ Yes ☐ No

12. Describe the results of any previous related trials:

13. Describe in complete detail any adverse results from previously related trials including animal studies and/or toxicity studies:

14. List all products that will be in human clinical trial phase during the next 12 months:
    (Please attach a copy of the protocol(s), including informed consent document(s))

Product	Description	# of patients	Trial phase	Trial length	Trial location

15. Identify the age and sex of the test subjects:

16. Detail the method in which test subjects will be recruited:

17. How will the trial be conducted and by whom?

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18. Provide a detailed explanation of the trial:

19. Detail any and all products involved with this trial:

20. What are the known and/or possible side effects?

21. How are test subjects notified of these side effects?

22. How will the trial be funded?

23. 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):*

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

25. Is applicant a member of this Board? ☐ Yes ☐ No

26. List the number of employed professionals or independent contractors:

	Employee	**Independent contractor**	**Total**
RN/LPN			
Lab technician			
Clinical investigator			
Clinical research associate			
Physician			
Medical monitor			
Engineer			
Data entry			
Legal counsel			
Other:			

27. Does applicant perform any environmental testing or consulting? ☐ Yes ☐ No
If "Yes", provide a detailed explanation:

28. 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 and steroids		
Vaccines		
Injectables		
Prescription products		
Over the counter		
Weight loss aids		

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	Last 12 months	Next 12 months
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		
Describe "Other":		

SECTION III – PRODUCTS AND DEVICES SECTION

1. Does applicant manufacture or sell any products? ☐ Yes ☐ No
   If "Yes", provide a detailed description of any current or future products that applicant anticipates:

2. List the name and proposed use or function of the product being tested or manufactured:

Products, devices and services *(list class for devices also)*	Applicant acts as a/an: M | W | R | I | MR	# of years	% of gross sales	Does applicant: Install | Repair or service	Products sold to M | W | R | I | MR	Projected # annual users	Annual revenue
			%				
			%				
			%				

M = Manufacturer W = Wholesaler R = Retailer I = Importer MR = Manfacturer Rep

3. Are any of applicant's products subject to registration, regulation, and/or review by any government agency? ☐ Yes ☐ No
   If "Yes", please explain:

4. What product(s) has applicant ceased manufacturing in the past 10 years?

5. Have any products been acquired by merger or acquisition? ☐ Yes ☐ No

SECTION IV – PROCESSING AND QUALITY CONTROL

1. Does applicant design and manufacture the complete product? ☐ Yes ☐ No
   If "No", describe products or components purchased:

2. Do any products, ingredients, or components originate from outside the United States? ☐ Yes ☐ No
   If "Yes", please specify the country(ies) of origin:

   Does applicant import these products or components directly? ☐ Yes ☐ No
   Are imported products and components tested for contamination and verification that they match what was ordered? ☐ Yes ☐ No

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3. Do others manufacture, assemble, or package products under the applicant's name or label? ☐ Yes ☐ No
If "Yes", please provide the name(s) and address(es) of the contract manufacturers:

4. Does applicant obtain COIs evidencing products liability insurance coverage from each manufacturer and supplier based in the United States? ☐ Yes ☐ No

5. Is applicant named as an additional insured vendor on each manufacturer's/supplier's product liability insurance? ☐ Yes ☐ No

6. Does applicant have written quality control and testing procedures in place? ☐ Yes ☐ No
If "Yes", how long are quality control and testing records retained?
Has applicant obtained any of the following quality registration(s)/certification(s)?
(Check all that apply): ☐ ISO 9000 ☐ ISO 9001 ☐ ISO 13485 ☐ QS 9000

7. Can applicant identify their product(s) from those of competitors? ☐ Yes ☐ No
If "Yes":
a. How are applicant's products identified from those of competitors?

b. Do applicant's records indicate the date of sale and purchaser of products? ☐ Yes ☐ No

8. Does applicant maintain complete inventory records of shipments and/or deliveries to consignees? ☐ Yes ☐ No
If "Yes", are serial and/or batch numbers shown on the finished product and on shipment invoices? ☐ Yes ☐ No

9. Does applicant have a specific program to withdraw known or suspected defective products from the market? ☐ Yes ☐ No

10. Has applicant recalled or considering recalling any product(s)? ☐ Yes ☐ No
If "Yes", please explain:

11. Provide date of applicant's last FDA inspection (month/year):
Was a FDA 483 form issued? ☐ Yes ☐ No
If "Yes", please attach the 483 form, applicant's response(s), and FDA acceptance of such response(s) as adequate.

SECTION V – PROFESSIONAL SERVICES

1. Provide percentages for the following professional services:

Service	%	Service	%
Clinical trials management	%	Product recall/withdrawal	%
Site phase 1 services	%	Equipment maintenance/sterilization	%
Clinical trials packaging	%	Quality systems and regulatory compliance	%
CLIA certified lab services	%	Sales and marketing	%
Communications and publications	%	Software development	%
Health management, economic, and policy research	%	Manufacture/distribution/packaging/mixing/labeling	%
Information services/databases	%	Pharmacoviligence/safety surveillance	%
Institutional Review Board	%	Pre-clinical development	%
Other *(please explain)*:			%

Details:

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SECTION VI – CURRENT INSURANCE			
1. Has applicant had previous insurance for this enterprise? If "Yes", complete the following:			☐ Yes ☐ No
Products liability		**Clinical testing liability**	
Current carrier		Current carrier	
Policy term		Policy term	
Premium		Premium	
Deductible/SIR		Deductible/SIR	
Primary and excess limits		Primary and excess limits	
Retro date		Retro date	
2. If excess coverage is being requested, please provide underlying policy terms and conditions:			

SECTION VII – REQUESTED COVERAGE		
1. Provide specifics for coverage desired:		
Coverage	**Limits requested**	**Deductible/SIR**
Premises and operations liability		
Products and completed operations		
Professional liability *(errors and omissions)*		
Other *(describe)*:		
2. If excess coverage is being requested, please provide underlying policy terms and conditions.		

SECTION VIII – CLAIM HISTORY		
1. During the past five (5) years, have any claims been presented to applicant's current or prior insurance carrier or presented directly to applicant? If "Yes", complete the following: *(If more than two claims, attach a separate sheet describing the losses.)*		☐ Yes ☐ No
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:		
2. Is applicant, or any other person for whom insurance is being requested, aware of any circumstances which may result in a claim?		☐ Yes ☐ No
3. In the past five (5) years, has applicant's insurance ever been cancelled or been non-renewed?		☐ Yes ☐ No
4. Has any license or accreditation ever been suspended, denied, or revoked?		☐ Yes ☐ No
5. Of what professional association(s) is applicant a member in good standing?		

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SECTION IX – MISCELLANEOUS

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

SECTION X – SIGNATURE, CONSENT AND AGREEMENT

This Application is the basis for coverage; therefore, any incorrect or incomplete statements or answers could nullify coverage. Completion of this form neither binds coverage nor guarantees that a policy will be issued. *(Not applicable in North Carolina)*

I hereby request that my application for insurance coverage be submitted for consideration to the company shown in this application. Accordingly, I authorize and direct any person or organization whatsoever to release and furnish to that company any and all information requested which may relate to my insurability.

I hereby indicate that the aforementioned statements and answers are correct and complete. I further understand that an incorrect or incomplete statement or answer could void my protection.

I hereby consent to the review by the company shown in this application of any incidents or occurrences likely to result in malpractice allegation or claim. I agree to cooperate in the review of claims and incidents which apply to the coverage requested.

Where applicable, I hereby consent to the review of my application by the committees appointed by my county or state professional association / society. I agree to cooperate with these committees.

COPY OF NOTICE OF INFORMATION PRACTICES (PRIVACY) HAS BEEN GIVEN TO THE APPLICANT.

(Not required in all states, contact your agent or broker for your state's requirements.)

Personal information about you, including information from a credit or other investigative report, may be collected from persons other than you in connection with this application for insurance and subsequent amendments and renewals. Such information as well as other personal and privileged information collected by us or our agents may in certain circumstances be disclosed to third parties without your authorization. Credit scoring information may be used to help determine either your eligibility for insurance or the premium you will be charged. We may use a third party in connection with the development of your score. You may have the right to review your personal information in our files and request correction of any inaccuracies. You may also have the right to request in writing that we consider extraordinary life circumstances in connection with the development of your credit score. These rights may be limited in some states. Please contact your agent or broker to learn how these rights may apply in your state or for instructions on how to submit a request to us for a more detailed description of your rights and our practices regarding personal information. *(Not applicable in AZ, CA, DE, KS, MA, MN, ND, NY, OR, VA, or WV. Specific ACORD 38s are available for applications in these states.)*

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.

FRAUD STATEMENTS

Applicable in AL, AR, DC, LA, MD, NM, RI and WV

Any person who knowingly (or willfully)* presents a false or fraudulent claim for payment of a loss or benefit or 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. **Applies in MD Only.*

Applicable in CO

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.

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Applicable in FL and OK

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

Applicable in KS

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 commits a fraudulent insurance act.

Applicable in KY, NY, OH and PA

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* (not to exceed five thousand dollars and the stated value of the claim for each such violation)*. **Applies in NY Only.*

Applicable in ME, TN, VA and WA

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 denial of insurance benefits. **Applies in ME Only.*

Applicable in NJ

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

Applicable in OR

Any person who knowingly and with intent to defraud or solicit another to defraud the insurer by submitting an application containing a false statement as to any material fact may be violating state law.

☐ ***I have read the statements above, understand their meaning and agree.***

Applicant's signature:
Date:
Applicant's name:
Applicant's title:

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