



**James River Insurance Company
and its Subsidiaries**

6641 West Broad Street, Suite 300
Richmond, VA 23230

Clinical Trials 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:

- Informed consent documents
- Sample protocol documents
- Copy of current facility license *(if applicable)*
- Copy of your current state inspection *(if applicable)*
- Sample contract between you and your clinical investigator *(if applicable)*

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	Revenue	Payroll	# of employees
Next year			
Last year			
2 nd year prior			
3 rd year prior			
4 th year prior			
5 th year prior			

SECTION II – CLINICAL TRIALS OPERATIONS

1. Does applicant manufacture or sell any products? ☐ Yes ☐ No
 If "Yes", please supply a detailed description of current products and any future products being researched:

2. Provide a complete description of applicant's operations and services rendered. Describe applicant's role in the clinical trials (*e.g., trial sponsor, research site, product manufacturer, etc.*):

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

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

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

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

a. Describe this phase:

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

c. Provide the Investigational New Drug (IND) number:

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

e. How will the trial be funded?

- f. Will this phase be conducted, and have all prior phases been conducted, in accordance with FDA approved protocol? ☐ Yes ☐ No
 If "No", please explain:

- g. Will applicant or applicant's employee provide any health care services in conjunction with this trial? ☐ Yes ☐ No
 If "Yes", please provide a description of the services that will be performed:

If "Yes", provide the professional title of the individuals who will perform these services:

7. List all on-going and pending human clinical trials to be conducted during the next 12 months:

Product	Description	# of participants	Trial phase	Trial length	Trial location

8. Identify age and sex of the test subjects:

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

10. Will test subjects be required to sign an informed consent document? <input type="checkbox"/> Yes <input type="checkbox"/> No If "Yes", attach a copy of the informed consent document. a. Does applicant require clinical investigators to test participants on their understanding of the informed consent document(s)? <input type="checkbox"/> Yes <input type="checkbox"/> No			
11. How are test subjects notified of any potential or known side effects?			
12. Are all trials overseen by an Institutional Review Board (IRB)? <input type="checkbox"/> Yes <input type="checkbox"/> No a. Is applicant a member of this board? <input type="checkbox"/> Yes <input type="checkbox"/> No			
13. Indicate below the testing that has been performed on specified products in the past 12 months and that is anticipated during the next 12 months:			
Type of product	Last 12 months	Next 12 months	
Hormones and steroids			
Vaccines			
Injectables			
Prescription products			
Over the counter (OTC) products			
Weight loss aids			
Vitamins			
Food supplements			
Novel drugs			
Generic off-patent			
Instruments (<i>excluding diagnostic</i>)			
Diagnostic instruments			
Surgical equipment			
Therapeutic devices			
Life support			
Cosmetic, health, beauty aids			
Other (<i>please describe</i>):			
14. List below the number of employed professionals or independent contractors:			
Title/position	Employee	Independent contractor	Total
RN/LPN			
Lab technician			
Clinical investigator			
Clinical research associate			
Physician			
Medical monitor			
Engineer			
Biostatistician			
Data entry			
Legal counsel			
Other (<i>please describe</i>):			
15. Is the clinical investigator an employee of your entity? <input type="checkbox"/> Yes <input type="checkbox"/> No			
16. Is the clinical investigator an employee of the test site facility? <input type="checkbox"/> Yes <input type="checkbox"/> No			
17. Do employed professionals carry their own medical malpractice coverage? <input type="checkbox"/> Yes <input type="checkbox"/> No			
a. If "Yes", what limits are required?			

18. Do independent contractors carry their own medical malpractice or professional coverage (*where required*)? ☐ Yes ☐ No
If "Yes", what limits are required?

SECTION III – CLINICAL TRIALS – APPLICANT HISTORY

1. Describe the results from any previous related trials:
2. Describe, in complete detail, any adverse results from previous related trials including animal studies and/or toxicity studies:
3. How many human clinical trials has applicant completed during the last three (3) years?
4. How many participants/subjects were enrolled in the human clinical trials completed during the last three (3) years?
5. What are the average annual expenditures for medical treatments for side effects sustained by human clinical trial participants over the last three (3) years?
6. Have any clinical trials been suspended or discontinued for safety reasons? ☐ Yes ☐ No
If "Yes", please explain:
7. Have any of applicant's clinical investigators been cited for regulatory violations? ☐ Yes ☐ No
If "Yes", please explain:
8. Has applicant had any evidence of serious regulatory non-compliance or fraud by applicant's clinical investigators or their staff during the last five (5) years? ☐ Yes ☐ No
If "Yes", please explain:
9. How many clinical trial "For Cause Audits" have been conducted by applicant, the FDA, or the Office for Human Research Protection (OHRP) during the last five (5) years?
10. Has applicant ever been inspected, surveyed, or audited by the FDA, the Center for Drug Evaluation and Research (CDER), or the Center for Biologics Evaluation and Research? ☐ Yes ☐ No
11. Has applicant ever been subject to any inquiry or investigation by any federal, state, or local agency concerning your professional services? ☐ Yes ☐ No
12. Has applicant ever been cited for any non-compliance with the FDA's Good Clinical Practice Guidelines or any other federal, state, or local law, ordinance, directive, or regulation? ☐ Yes ☐ No

SECTION IV – PRIOR INSURANCE AND CLAIMS HISTORY

1. Provide insurance information for the past three (3) years:

Carrier	Limits	Deductible	Retro date	Premium	Exposure base or policy rate

2. Has any claim been made against any person(s) or organization(s) to be covered under this insurance during the last five (5) years? ☐ Yes ☐ No
- If "Yes", please provide five (5) year loss history for all claims below and attach a description for any loss greater than \$10,000.

Year	# of claims	Total paid	Total reserves	Total incurred	Valuation date

SECTION V – 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.

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: