Beazley BioSecure™ Application

NOTICE: PART OR ALL OF THE POLICY FOR WHICH THIS APPLICATION IS MADE IS WRITTEN ON A CLAIMS MADE BASIS, WHICH MEANS THAT THE POLICY APPLIES ONLY TO ANY CLAIM FIRST MADE AGAINST THE INSURED DURING THE POLICY PERIOD OR THE OPTIONAL EXTENDED REPORTING PERIOD, IF APPLICABLE. AMOUNTS INCURRED AS CLAIMS EXPENSES SHALL REDUCE AND MAY EXHAUST THE LIMIT OF LIABILITY AND ARE SUBJECT TO THE DEDUCTIBLE. PLEASE READ THE POLICY CAREFULLY.

1. Answer ALL questions completely, leaving no blanks. If any questions, or part thereof, do not apply, print N/A in the space. *Any question left unanswered will be interpreted as a confirmation by applicant that it does not apply.*
2. If additional space is needed to answer any question fully, please attach a separate page.
3. This application will be attached to and made part of any policy issued.

PLEASE PROVIDE THE FOLLOWING INFORMATION:

1. Loss History for the last TEN years. The loss run should be updated within the last 30 days and include a breakdown of total incurred losses (paid and reserves for both indemnity and expense), and a description of all losses, whether paid or outstanding.
2. Most recent AUDITED financial statements.
3. Specimen copy of contractual agreements with independent contractor physicians and/or hospitals and/or laboratories.
4. Most recent local and/or State accreditation agency reports (if applicable).
5. A detailed description of applicant's operations.
6. Any marketing brochures or literature detailing services provided.
7. Copies of standard contracts between applicant and trial sponsors, 3rd parties and subcontractors.

1. GENERAL INFORMATION

a) Applicant Information

Applicant's name and address:	
Mailing address: (*if different from above*)	
Applicant's web address:	
Contact name and title:	

Contact phone number and email:	
Applicant is (please check one)	Business Organization: ☐ Partnership ☐ Limited Liability Corporation ☐ Individual ☐ Corporation ☐ Joint Venture ☐ Publicly Traded (Exchange: _____) ☐ Other _____
Applicant's business operations	
Years in business	
Parent company	
Please list all mergers or acquisitions within the last 6 years	
Does applicant have any plans for any mergers, acquisitions or consolidations in the next 12 months?	
Please list all requested Additional Insureds with their relationship	
Please list all subsidiaries and owned entities of applicant, and attach an entity organizational relationship chart	

b) Broker Information

Name	
Firm	
Address	

Phone	
Email	

c) Financial Information – please provide the following:

	Current Fiscal Year	Prior Fiscal Year
Current assets		
Total assets		
Net assets/equity		
Long term debt		
Gross annual revenues		
Net revenues/income		
Total cash and cash equivalents		

d) Sales History:

Projected next 12 months	Past 12 months	1st year prior	2nd year prior	3rd year prior

Has applicant had any clients that represent 10% or more of its total annual revenues in the last 5 years?
☐ Yes ☐ No Details:

Name	Maximum % of revenue in any one year

Number of employees: _____

Is applicant a member of any trade organization? ☐ Yes ☐ No

Please check all that apply: ☐ AHPA ☐ ABC ☐ NPA ☐ UNPA ☐ AAHP ☐ Other

2. RISK MANAGEMENT, CLAIMS HANDLING & LOSS CONTROL

a) Does applicant have a full time risk manager on staff? ☐ Yes ☐ No

Name	
Title	
Telephone	
Qualifications	
Length of tenure	

b) Does applicant have a formal, written risk management/loss prevention program? ☐ Yes ☐ No
Details: _____

c) Does applicant require new employees to participate in a training program that instructs them on all applicable company policies and procedures? ☐ Yes ☐ No
Details: _____

d) Does the applicant handle claims in-house or utilise the services of a third party administrator?
☐ Yes ☐ No Details: _____

e) Does applicant require a certificate of insurance evidencing products liability coverage and relevant limits from each product sponsor? ☐ Yes ☐ No

f) Does applicant require all Principal Investigators/subcontractors to carry their own medical malpractice liability insurance? ☐ Yes ☐ No
If so, please list the minimum limits: _____

g) Are all of applicant's trials subject to oversight by an Institutional Review Board? ☐ Yes ☐ No
If no, please explain: _____

h) Does applicant have written procedures governing the conduct of research? ☐ Yes ☐ No

i) Does applicant have a conflict of interest policy? ☐ Yes ☐ No

j) Is Good Clinical Practice training required for all clinical research personnel? If so, where is the documentation maintained?
☐ Yes ☐ No Documentation maintained: _____

k) Does applicant incorporate financial disclosures into the informed consent form procedure?
☐ Yes ☐ No

l) Do applicant's Clinical Investigators enrol their own study participants? ☐ Yes ☐ No

m) Do applicant's Clinical Investigators receive enrollment bonuses or participant referral fees, or stock in applicant's company or a position therein? ☐ Yes ☐ No

n) Does applicant provide Clinical Investigators, CROs or Sites with compensation other than charges for specific services rendered (ie, enrollment bonuses, equity interest, etc.)?
☐ Yes ☐ No

o) Does applicant compensate study participants? ☐ Yes ☐ No

3. REGULATORY/SAFETY

a) To the best of its knowledge is applicant in compliance with all applicable FDA regulations and/or those of applicable foreign agency equivalent? ☐ Yes ☐ No

b) When was applicant's most recent FDA Inspection? _____
What was the result? _____
Please attach copy of any 483 and your documented response.

c) Has applicant had any clinical trials placed on hold? ☐ Yes ☐ No
Details: _____

d) Have there been any clinical trials involving applicant's products which have been discontinued or suspended in whole or in part for safety reasons? ☐ Yes ☐ No
Details _____

e) Have any warning letters been issued against applicant or any of its investigators in the last 5 years? ☐ Yes ☐ No Details _____

f) Has applicant experienced any evidence of serious regulatory non-compliance or fraud by applicant's clinical investigators and their staff in the past five (5) years? ☐ Yes ☐ No
Details: _____

g) Have any clinical investigators been cited for regulatory violations in connection with applicant's trials? ☐ Yes ☐ No Details _____

h) How many clinical trial "For Cause Audits" have been conducted by applicant or any regulatory agency in the last five years? Details _____

i) Does applicant comply with the FDA requirements concerning financial disclosures?
☐ Yes ☐ No

j) What is the maximum compensation offered by applicant to trial participants?_____

k) Does applicant comply with all applicable state regulations regarding human clinical trials?
☐ Yes ☐ No

l) Please list all states in which applicant is operating.
_____

m) Is applicant licensed in the states in which it is operating? ☐ Yes ☐ No

n) Is applicant currently licensed by Federal and/or State Government? ☐ Yes ☐ No
Details: _____

SPONSORED CLINICAL TRIALS

(Please provide the protocol and informed consent for each listed trial.)

(Please use attachment if necessary)

Product	Protocol name and number	Phase of trial	Number of subjects last policy period	Number of subjects upcoming policy period	Indication	City and country

1. Clinical Trials involving persons under the age of 18: _____
2. Total number of clinical trial subjects in the past three (3) years: _____
3. Number of expanded access/compassionate use subjects anticipated: _____

PRODUCT TESTED

Drugs/Biologics:

Are any of the products applicant is testing or has tested in the last five (5) years:

Known teratogen ☐ YES ☐ NO Details _____

Known mutagen ☐ YES ☐ NO Details _____

Known carcinogen ☐ YES ☐ NO Details _____

Addictive ☐ YES ☐ NO Details _____

Known cytoxen ☐ YES ☐ NO Details _____

Medical Devices:

Are any of the products applicant is testing or has tested in the last five (5) years:

Cold Therapy ☐ YES ☐ NO Details _____

Implantable ☐ YES ☐ NO Details _____

Pain Management ☐ YES ☐ NO Details _____

Radiation-emitting ☐ YES ☐ NO Details _____

4. COVERAGE HISTORY

a) Please provide details of product/general liability coverage purchased in the last five (5) years to date:

Clinical Research Services:

Policy Period	Carrier	Limits	Retention	Premium	CM or Occ

Healthcare Professional Services:

Policy Period	Carrier	Limits	Retention	Premium	CM or Occ

Products-Completed Operations Liability:

Policy Period	Carrier	Limits	Retention	Premium	CM or Occ

General Liability:

Policy Period	Carrier	Limits	Retention	Premium	CM or Occ

Clinical Trials Medical Expenses:

Policy Period	Carrier	Limits	Retention	Premium	CM or Occ

Clinical Trials Medical Monitoring Expenses:

Policy Period	Carrier	Limits	Retention	Premium	CM or Occ

Has applicant's insurance ever been cancelled or non-renewed? ☐ Yes ☐ No

If Yes, please list the reasons for each such cancellation on a separate page

5. COVERAGE REQUESTED

Coverage	Limits	Deductible	Retroactive date
Clinical Research Services			
Healthcare Professional Liability			
Products/Completed Operations			
General Liability			
Medical Expense			
Medical Monitoring			

6. LOSS HISTORY

Please provide details of applicant's total aggregate losses, from the 1st dollar, including expenses (and please also attach hard copy loss runs):

Carrier	Policy year	Number of claims	Total indemnity incurred	Total expense incurred

1. Has any claim or suit for an error, omission or malpractice ever been made against applicant or any employees/staff working on its behalf? ☐ Yes ☐ No

   If yes, how many? _____ Please list each on a Supplemental Claim form.

2. Is (are) any person(s) or organization(s) proposed for this insurance aware of any fact, incident, circumstance, situation, condition, defect or suspected defect which may result in a claim against applicant, or any records request from any attorney? ☐ Yes ☐ No

   If yes, how many? _____ Please list each on a Supplemental Claim form.

3. Has applicant or any of its staff's license to practice medicine or license to prescribe or dispense drugs ever been limited, suspended, revoked, placed on probation or been voluntarily surrendered in any state? ☐ Yes ☐ No

   If yes, please attach explanation.

THE UNDERSIGNED IS AUTHORIZED BY THE APPLICANT AND DECLARES THAT THE STATEMENTS SET FORTH HEREIN AND ALL WRITTEN STATEMENTS AND MATERIALS FURNISHED TO THE INSURER IN CONJUNCTION WITH THIS APPLICATION ARE TRUE. SIGNING OF THIS APPLICATION DOES NOT BIND THE APPLICANT OR THE INSURER TO COMPLETE THE INSURANCE, BUT IT IS AGREED THAT THE STATEMENTS CONTAINED IN THIS APPLICATION, ANY SUPPLEMENTAL ATTACHMENTS, AND THE MATERIALS SUBMITTED HEREWITH ARE THE BASIS OF THE CONTRACT SHOULD A POLICY BE ISSUED AND HAVE BEEN RELIED UPON BY THE INSURER IN ISSUING ANY POLICY.

THIS APPLICATION AND MATERIALS SUBMITTED WITH IT SHALL BE RETAINED ON FILE WITH THE INSURER AND SHALL BE DEEMED ATTACHED TO AND BECOME PART OF THE POLICY IF ISSUED. THE INSURER IS AUTHORIZED TO MAKE ANY INVESTIGATION AND INQUIRY IN CONNECTION WITH THIS APPLICATION AS IT DEEMS NECESSARY.

THE APPLICANT AGREES THAT IF THE INFORMATION SUPPLIED ON THIS APPLICATION CHANGES BETWEEN THE DATE OF THIS APPLICATION AND THE EFFECTIVE DATE OF THE INSURANCE, THE APPLICANT WILL, IN ORDER FOR THE INFORMATION TO BE ACCURATE ON THE EFFECTIVE DATE OF THE INSURANCE, IMMEDIATELY NOTIFY THE INSURER OF SUCH CHANGES, AND THE INSURER MAY WITHDRAW OR MODIFY ANY OUTSTANDING QUOTATIONS OR AUTHORIZATIONS OR AGREEMENTS TO BIND THE INSURANCE

I HAVE READ THE FOREGOING APPLICATION OF INSURANCE AND ANY ATTACHMENT AND REPRESENT THAT THE RESPONSES PROVIDED ON BEHALF OF THE APPLICANT ARE TRUE AND CORRECT.

WARNING

ANY PERSON WHO, WITH INTENT TO DEFRAUD OR KNOWING THAT (S)HE IS FACILITATING A FRAUD AGAINST THE INSURER, SUBMITS AN APPLICATION OR FILES A CLAIM CONTAINING A FALSE OR DECEPTIVE STATEMENT MAY BE GUILTY OF INSURANCE FRAUD.

Signed: _____

Date: _____

Print Name: _____

Title: _____

(Owner, Partner, Authorized Officer)

If this Application is completed in Florida, please provide the Insurance Agent's name and license number. If this Application is completed in Iowa or New Hampshire, please provide the Insurance Agent's name and signature only.

Agent's Printed Name: _____

Florida Agent's License Number: _____

Agent's Signature: _____

*If you are electronically submitting this document, apply your electronic signature to this form by checking the Electronic Signature and Acceptance box below. By doing so, you agree that your use of a key pad, mouse, or other device to check the Electronic Signature and Acceptance box constitutes your signature, acceptance, and agreement as if actually signed by you in writing and has the same force and effect as a signature affixed by hand.

☐ Electronic Signature and Acceptance – Authorized Representative

☐ Electronic Signature and Acceptance - Producer

COLORADO: It is unlawful to knowingly provide false, incomplete, or misleading facts or information to an insurer to defraud or attempt to defraud the insurer. Penalties may include imprisonment, fines, denial of insurance, and civil damages. Any insurer or agent of an insurer 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.

DISTRICT OF COLUMBIA: 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 and an insurer may deny insurance benefits if false information materially related to a claim made 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 in the third degree.

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

MAINE, TENNESSEE, VIRGINIA AND WASHINGTON: It is a crime to knowingly provide false, incomplete or misleading information to an insurer to defraud the insurer. Penalties may include imprisonment, fines or denial of insurance benefits.

MINNESOTA: A person who files a claim with intent to defraud or helps commit a fraud against an insurer is guilty of a crime.

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

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.

NEW YORK AND KENTUCKY: Any person who knowingly and with intent to defraud an insurer or other person files an application for insurance or statement of claims 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. New York applicants are subject to a civil penalty not to exceed $5,000 and the stated value of the claim for each such violation. Pennsylvania applicants are subject to criminal and civil penalties.

HEALTHCARE PROFESSIONAL LIABILITY SUPPLEMENT

Medical Staff Profile/ Schedule of Physicians, Surgeons, Osteopaths, Podiatrists, Orthodontists, Chiropractors, Psychiatrists, Psychologists or Dentists – on Staff or Contracted: (supply separate sheet if necessary)

Name	Specialty	Board Certification	Hours Worked	Volunteer, Contract, Employed	Own Malpractice Insurance?	Medical Director?

1. Are any of the above-listed physicians to be listed under applicant's policy? ☐ Yes ☐ No
   (If yes, please attach CV or application for each physician)

2. Is physician credentialing and privileging formalized and documented? ☐ Yes ☐ No

3. Do any of the physicians have direct patient care responsibilities? ☐Yes ☐ No
   (If yes, what is the physician's role in providing services for applicant's facility?)_____

Please provide details of all other staff utilized:

Health Professional	Employed			Contracted		
	Full Time	Part Time	Hours	Full Time	Part Time	Hours
Registered Nurses						
Licensed Practical Nurses						
Licensed Vocational Nurses						
Nurse Practitioners						
Physician Assistants						
Certified Nursing Assistants						
Physical, Occupational, and Speech Therapists						
Home Health Aides						
Sitters/Companions						
Emergency Medical Technicians						
Paramedics						

Pharmacists						
Technicians						
Social Workers						
Other (please provide description)						

CREDENTIALING

a) Are all health professionals (including subcontractors) credentialed prior to hiring? ☐ Yes ☐ No

b) How often are physicians re-credentialed? Every ____ years

c) Prior to hiring any employee, does applicant verify:

i) Education background and training? ☐ Yes ☐ No

ii) Employment references with at least two previous employers? ☐ Yes ☐ No

iii) Criminal record, on a Local, State and National scale? (Please indicate which apply)

Local ☐ Yes ☐ No

State ☐ Yes ☐ No

National ☐ Yes ☐ No

iv) Driving record? ☐ Yes ☐ No

v) Credit record? ☐ Yes ☐ No

vi) Drug tests? ☐ Yes ☐ No

a) Does applicant keep all information on file and verify its completion prior to employment commencement? ☐ Yes ☐ No

b) Please list associations which applicant is currently a member:

Name	Member since:
American Hospital Association	
Federation of American Hospitals	
State Hospital Association	
merican Nursing Home Association	
JCO	
Other:	

CLINICAL RESEARCH ORGANIZATIONS/ SITE MANAGEMENT ORGANISATION SUPPLEMENT

Are Human Clinical Trials activities performed at more than one location operated by applicant? If so:	☐ Yes ☐ No
Is there any corporate oversight with regard to site management policies and procedures?	☐ Yes ☐ No
Are there standard operating procedures applicable to all sites?	☐ Yes ☐ No
Is there a formalised reporting procedure that requires all site medical directors to report to a corporate medical director for supervision, training, and guidance?	☐ Yes ☐ No
Is there a formalised reporting procedure for clinical site managers to report to a corporate clinical site manager or medical director?	☐ Yes ☐ No
Please indicate the following with regard to participant-informed consent documents and documentation policies and procedures:	
Is there a written procedure requiring the Principal Investigator orally to review the informed consent documents with each participant and test them for their understanding, which conforms to FDA guidelines?	☐ Yes ☐ No
Is there a procedure to check the trial participant's understanding of the informed consent?	☐ Yes ☐ No
Is this conversation properly documented?	☐ Yes ☐ No
Are participant medical records maintained in a secure area?	☐ Yes ☐ No
Are backup medical records stored off-site in hard copy or digitally?	Hard copy ☐ Digitally ☐
For how long are such participant medical records maintained by applicant?	
Please explain applicant's procedures for disqualifying participants from a trial after it has started.	
Who communicates this decision to the participant and where is it documented?	
Please explain applicant's procedures concerning the periods between dosing different participants with first-time use trial drugs/medical devices.	

CRO/SMO SUPPLEMENT CONTINUED

SERVICE PROFILE

Type of Human Clinical Trial Activities/Clinic Visits	Total Beds	Average Occupied Beds	HCT Outpatient Visits
Pre-Clinical			
Phase I-IIa			
Phase II b			
Phase III			
Phase IV			
Services limited to blood draws only			
Non-biomedical research, social sciences research, government-sponsored research			

Please indicate if any trials involve or have involved the following:	Yes	No
Cognitively Impaired		
Elderly		
Minors (under 18)		
Pregnant Women		
Prisoners		

Please clarify and expand upon any positive answer to the above.

a) Total number of completed human clinical trials performed by applicant in the last 3 years ____

b) Total number of human test subjects enrolled by applicant in the last 3 years ____

c) Do any of applicant's employees provide direct patient care on applicant's behalf?
☐ Yes ☐ No

If so, do they carry their own medical malpractice insurance?
☐ Yes ☐ No Limits _____

d) Does applicant ever act as both trial sponsor and clinical investigator? ☐ Yes ☐ No