



Beazley BioSecure™

CLINICAL RESEARCH SERVICES, HEALTHCARE PROFESSIONAL SERVICES, PRODUCTS/COMPLETED OPERATIONS, GENERAL LIABILITY, CLINICAL TRIAL MEDICAL EXPENSES, AND CLINICAL TRIAL MEDICAL MONITORING EXPENSES CLAIMS MADE INSURANCE

NOTICE: This is a Claims Made **Policy**. Except to such extent as may otherwise be provided, the coverage under this **Insurance** is limited to those **Claims** which are first made against the **Insured** during the **Policy Period**.

Please review the coverage provided by this **Insurance** carefully and discuss it with your insurance agent or broker.

In consideration of the payment of premium and in reliance upon the statements, representations and warranties made in the application which is made a part of this **Insurance Policy** and subject to the Limit of Liability, Exclusions, limitations, conditions and other terms of this **Insurance**, the Underwriters agree with the **Named Insured** as follows:

I. INSURING AGREEMENTS

The Underwriters shall pay a **Claim** under this **Policy** only if that **Claim**:

1. arises out of an **Accident** or negligent act, error or omission that takes place after the Retroactive Date and before the Expiration Date;
2. is first made against any **Insured** during the **Policy Period**; and
3. falls within one of the Insuring Agreements A. 1-6 below and coverage under that Insuring Agreement has been purchased by the **Insured**.

A. Coverage

1. Clinical Research Services

The Underwriters will pay on behalf of the **Insured Damages** and **Claims Expenses** which the **Insured** shall become legally obligated to pay, arising out of any negligent act, error or omission of the **Insured** in rendering or failing to render **Clinical Research Services** on behalf of the **Named Insured**.

2. Healthcare Professional Services

The Underwriters will pay on behalf of the **Insured Damages** and **Claims Expenses** which the **Insured** shall become legally obligated to pay, for **Bodily Injury** arising out of any negligent act, error or omission of the **Insured** in rendering or failing to render **Healthcare Professional Services** on behalf of the **Named Insured**.

3. Products/Completed Operations Liability

The Underwriters will pay on behalf of the **Insured Damages** and **Claims Expenses** which the **Insured** shall become legally obligated to pay, for **Bodily Injury** or **Property Damage** caused by an **Accident** arising out of the **Products/Completed Operations Liability Hazard**.

4. General Liability

The Underwriters will pay on behalf of the **Insured Damages** and **Claims Expenses** which the **Insured** shall become legally obligated to pay, for **Bodily Injury**, **Personal Injury**, **Property Damage** or **Advertising Liability** caused by an **Accident**.

5. Clinical Trial Medical Expenses

The Underwriters will pay on behalf of the **Insured Clinical Trial Medical Expenses** for **Bodily Injury** arising out of any negligent act, error or omission of the **Insured** in or resulting from the rendering or failure to render **Clinical Research Services** or **Healthcare Professional Services** on behalf of the **Named Insured**.

Provided that:

- i. the **Clinical Trial Medical Expenses** are incurred and reported to the Underwriters' entity designated in Item 9 of the Declarations within 3 months of the date of the **Bodily Injury**; and
- ii. the injured person submits to examination, at the Underwriters' expense, by physicians of the Underwriters' choice as often as the Underwriters reasonably require. The Underwriters' rights of examination are discretionary and not obligatory and do not give rise to any obligation or duty of care to the claimant.

6. Clinical Trial Medical Monitoring Expenses

The Underwriters will pay on behalf of the **Insured Clinical Trial Medical Monitoring Expenses** arising out of any negligent act, error or omission of the **Insured** or resulting from the rendering or failure to render **Clinical Research Services**.

Provided that:

- i. the claimant's participation in a **Clinical Trial** has given rise to a substantial risk that the claimant will sustain **Bodily Injury** at some point, so that medical testing and monitoring is warranted either to prevent, reduce the risk of, or to treat such probable **Bodily Injury**; and
- ii. the claimant submits to examination, at the Underwriters' expense, by physicians of the Underwriters' choice as often as the Underwriters reasonably require. The Underwriters' rights of examination are discretionary and not obligatory and do not give rise to any obligation or duty of care to the claimant.

B. Defense and Settlement

1. The Underwriters shall have the right and duty to defend the **Insured** for any **Claim** first made against the **Insured**, even if any of the allegations of the **Claim** are groundless, false or fraudulent. The Underwriters shall choose defense counsel in conjunction with the **Insured**, but in the event of a dispute the decision of the Underwriters is final.
2. The Limit of Liability available to pay **Damages** shall be reduced and may be completely exhausted by payment of **Claims Expenses**. **Damages** and **Claims Expenses** shall be applied against the Deductible.
3. The Underwriters shall have the right to make any investigation they deem necessary, including any investigation with respect to coverage and any application for this **Insurance**.
4. If the **Insured** refuses to consent to any settlement or compromise recommended by the Underwriters and acceptable to the claimant, and elects to contest or continue to contest the **Claim**, the Underwriters' liability for any **Damages** and **Claims Expenses** shall not exceed the amount for which the **Claim** could have been settled, less the remaining Deductible, but including the **Claims Expenses** incurred up to the time of such refusal, or the applicable

Limit of Liability, whichever is less, and the Underwriters shall have the right to withdraw from the defense of the **Claim** by tendering control of such defense to the **Insured** without further liability.

5. The Underwriters shall pay all premiums on bonds to release attachments and all premiums on appeal bonds required in any such defended suit but without any obligation to apply for or furnish such bonds, all costs taxed against the **Insured** in any suit, and all interest accruing after entry of final judgment until the Underwriters have paid, tendered or deposited in court part of such judgment as does not exceed the Limit of Liability.
6. The Underwriters shall reimburse the **Insured** for all reasonable expenses, other than loss of earnings, incurred at the Underwriters' request.
7. The Underwriters shall not be obligated to pay any **Damages** or **Claims Expenses**, or to undertake or continue the defense of any **Claim**, after the applicable Limit of Liability has been exhausted by payment of **Damages** or **Claims Expenses** or after deposit of the remaining applicable Limit of Liability in a court of competent jurisdiction, and that upon such payment the Underwriters shall have the right to withdraw from the further defense of the **Claim** by tendering control of such defense to the **Insured** without further liability.
8. Notwithstanding anything to the contrary in this Section I. B, with respect to any **Claim** brought outside the United States, its territories or Puerto Rico, or Canada, the **Insured** shall (and the Underwriters shall not) be obligated to assume charge of the defense and pay the **Claims Expenses** of any such **Claim**. The Underwriters, however, shall approve in writing the retention of any defense counsel and participate with the **Insured** in the choice of arbitrators or mediators. The Underwriters shall also be kept fully informed, or have a designated representative kept fully informed, by the **Insured** concerning the conduct of and all material factors or events relevant to such defense or such arbitration or mediation.

Solely with respect to any **Claim** brought outside the United States, its territories or Puerto Rico, or Canada, the Underwriters will reimburse the **Insured** for, or at the Underwriters' sole discretion, pay on the **Insured's** behalf, those sums that the **Insured** becomes legally obligated to pay as **Damages** and **Claim Expenses** to which this **Insurance** applies.

9. The **Insured** shall at all times make available to the Underwriters such information and access to records as the Underwriters shall require.

II. INSUREDS

Each of the following is an **Insured** under this **Insurance** to the extent set out below:

- (a) The organization, partnership, joint venture, or limited liability company named in Item 1. of the Declarations is a **Named Insured** under this **Policy**. Any partners or members thereof are also **Insureds** but solely with respect to the conduct of the **Named Insured's** business and solely while acting within the scope of their duties for such organization, partnership, joint venture, or limited liability company.

The following are also **Insureds**:

- (1) an executive officer, director or stockholder solely while acting within the scope of their professional duties as such;
- (2) an **Employee**, student, or **Volunteer** of the **Named Insured** while acting within the scope of their duties as such, except that no **Employee**, student or **Volunteer** is an **Insured** in connection with their participation as a **Patient**;

However, the insurance afforded to any **Employee** does not apply to:

a. **Bodily Injury** to:

- (i) a co-employee of the **Insured** arising out of or in the course of his employment or while performing duties related to the conduct of the **Insured's** business;
- (ii) the **Insured** or the **Insured's** partners or members, if applicable;

b. **Property Damage** to property:

- (i) owned, occupied or used by; or
- (ii) rented to, in the care, custody or control of, or over which physical control is being exercised for any purpose by:

the **Insured** or any of the **Insured's** employees or any partner or member;

- (3) a Clinical Research Associate, Clinical Research Consultant, Clinical Research Coordinator, Clinical Research Monitor, members

of any Institutional Review Board, if the **Named Insured** is required, pursuant to a written contract or agreement executed prior to the date of commencement of the relevant **Clinical Research Services** or **Clinical Trial**, to indemnify such person or organization;

- (4) a **Principal Investigator**, individual physician, surgeon, osteopath, podiatrist, orthodontist, chiropractor, psychiatrist, psychologist or dentist, if the **Named Insured** is required, pursuant to a written contract or agreement executed prior to the **Accident** giving rise to the related **Claim**, to indemnify them;
- (5) any individual providing the following services if the **Named Insured** is required, pursuant to a written contract or agreement executed prior to the date of commencement of such services, to indemnify such person or organization:
 - (i) quality/regulatory compliance;
 - (ii) data management (except as excluded by IV. 4. (a) (2) or IV.2. (r));
 - (iii) medical writing;
 - (iv) statistical management; or
 - (v) quality assurance;

but solely for the rendering or failure to render **Clinical Research Services** or **Healthcare Professional Services** and while acting in accordance with any and all documented protocols, policies and procedures established and/or followed by the **Named Insured**, and within the scope of their duties as such;

- (b) any person who previously qualified as an **Insured** under II. (a) above prior to the termination of the required relationship with the **Named Insured**, but solely with respect to:
 - (1) **Clinical Research Services** performed on behalf of the **Named Insured**;
 - (2) **Healthcare Professional Services** performed on behalf of the **Named Insured**; or
 - (3) an **Accident** arising solely out of the **Named Insured's Products** or **Named Insured's Operations**;

which were performed or which occurred prior to the termination of the required relationship with the **Named Insured**;

- (c) the estate, heirs, executor, administrators, assigns and legal representatives of any **Insured** in the event of the **Insured's** death, incapacity, insolvency or bankruptcy, but only to the extent that such **Insured** would otherwise be provided with coverage under this **Policy**;
- (d) solely with respect to the coverage provided under Insuring Agreement I.A.3. (Products/Completed Operations Liability), any person who or organization that is a vendor of the **Named Insured** (hereinafter referred to as the "Vendor"), but only with respect to the sale in the regular course of the Vendor's business of the **Named Insured's Products** if the **Named Insured** is required, pursuant to a written contract or agreement executed prior to such sale, to provide such person or organization with such coverage. However, any such coverage afforded to the Vendor shall not apply to any liability arising out of:
 - (1) any warranty or representation unauthorized by the **Named Insured**;
 - (2) any act of the Vendor which changes the condition or composition of the **Named Insured's Products**;
 - (3) any failure to maintain the **Named Insured's Products** in a merchantable condition;
 - (4) any assumption of liability by the Vendor in any contract or agreement, provided, however, that this provision shall not apply to any liability for **Damages** that the Vendor would have in the absence of such contract or agreement;
 - (5) any failure to make such inspections, adjustments, tests or servicing as the Vendor has agreed to make or normally undertakes to make in the usual course of business, in connection with the distribution or sale of the **Named Insured's Products**, or any failure to remove from sale or distribution the **Named Insured's Products** once the shelf life or expiration date of such product has been reached;
 - (6) any **Named Insured's Products** which after distribution or sale by the **Named Insured** have been labeled or relabeled or used as a container, part or ingredient of any other product, thing or substance by or for the Vendor;
 - (7) the sole negligence of the Vendor for its own acts, errors or omissions or those of its employees or anyone else acting on its

behalf; however, this exclusion does not apply to those inspections, adjustments, tests or servicing that the Vendor has agreed to undertake or normally undertakes in the usual course of business, in connection with the distribution or sale of the **Named Insured's Products**; or

- (8) liability arising out of any products or any ingredient, part or container, entering into, accompanying or containing such products acquired by the **Named Insured** from the Vendor.
- (e) solely with respect to the coverage provided under Insuring Agreement I.A.3. (Products/Completed Operations Liability), any person who or organization that is a medical sales consultant of the **Named Insured** (hereinafter referred to as "Medical Sales Consultant"), but only with respect to the sale or distribution of the **Named Insured's Products** if the **Named Insured** is required, pursuant to a written contract or agreement executed prior to such sale or distribution, to provide such person or organization with such coverage. However, any such coverage afforded to the Medical Sales Consultant shall not apply to:
- (1) such Medical Sales Consultant's activities unless:
 - (i) the **Damages** arise directly out of the use of the **Named Insured's Products**; and
 - (ii) the **Damages** do not arise out of the Medical Sales Consultant's willful violation of any law or regulation; and
 - (iii) the **Damages** arise out of the assumption of such liability by the **Named Insured** in its written contract with the Medical Sales Consultant;
 - (2) liability arising out of any physical or chemical change in the **Named Insured's Product** made intentionally by any person or entity without the **Named Insured's** consent;
 - (3) any assumption of liability by the Medical Sales Consultant in any contract or agreement, provided, however, that this provision shall not apply to any liability for **Damages** that the Medical Sales Consultant would have in the absence of such contract or agreement;
 - (4) the Medical Sales Consultant's sole negligence;
 - (5) any **Healthcare Professional Services** provided by the Medical Sales Consultant;

- (6) any warranty or representation made without the authorization of the **Named Insured**; or
- (7) liability arising out of any products or any ingredient, part or container, entering into, accompanying or containing such products acquired by the **Named Insured** from the Medical Sales Consultant;
- (f) any additional independent contractor, person or entity scheduled in Item 10 of the Declarations.
- (g) This **Policy** shall not apply:
 - (i) to any liability of an **Insured** for his or her acts, errors or omissions outside the scope of work conducted for or on behalf of the **Named Insured**; or
 - (ii) to any liability arising out of the conduct of any partnership or joint venture of which the **Insured** is a partner or member and which is not designated in this **Policy** as a **Named Insured**.

III. TERRITORY

This **Insurance** applies anywhere in the world regardless of where the negligent acts, errors, omissions or **Accidents** take place or where a **Claim** is brought.

Solely with respect to any **Claim** brought outside the United States, its territories or possessions, Puerto Rico, or Canada, it is agreed that this **Insurance** is not a substitute for any admitted insurance required by any foreign jurisdiction. The Underwriters assume no responsibility for the furnishing of certificates, evidence of insurance, or bonds in any country in which the Underwriters are not an admitted or authorized insurer. The Underwriters shall not be liable for any fine or penalty, imposed upon the **Insured** or any person or entity insured under this **Policy**, for failing to obtain insurance from an admitted or authorized insurer nor for any other failure to comply with an insurance law of a jurisdiction in which the Underwriters are not an admitted or authorized insurer.

IV. EXCLUSIONS

1. Exclusions applicable to Insuring Agreements I.A.1, Clinical Research Services and I.A.2, Healthcare Professional Services

The coverage under Insuring Agreements I.A.1 and I.A.2 of this **Policy** does not apply to **Damages** or **Claims Expenses** incurred with respect to any **Claim**:

- (a) for **Bodily Injury, Personal Injury, Property Damage or Advertising Liability** based upon or arising out of the **Named Insured's Products**;
- (b) arising out of **Personal Injury, Property Damage or Advertising Liability**, except with respect to **Bodily Injury** arising out of any negligent act, error or omission of any **Insured** in the rendering or failing to render **Clinical Research Services or Healthcare Professional Services**;
- (c) arising out of any criminal, dishonest, fraudulent or malicious act, error or omission of any **Insured**, committed with actual criminal, dishonest, fraudulent or malicious purpose or intent. However, the insurance afforded by this **Policy** shall apply to **Claims Expenses** incurred in defending any such **Claim** alleging the foregoing until such time as there is a final adjudication, judgment, binding arbitration decision or conviction against the **Insured**, or admission by the **Insured**, establishing such conduct at which time the **Named Insured** shall reimburse the Underwriters for all **Claims Expenses** incurred defending the **Claim** and the Underwriters shall have no further liability for **Claims Expenses**;
- (d) based upon an express or implied warranty or guarantee, or breach of contract in respect of any agreement to perform work for a fee;
- (e) arising out of any **Insured's** activities as a trustee, partner, officer, director or employee of any trust, charitable organization, corporation, company or business other than that of the **Named Insured**;
- (f) arising out of actual or alleged plagiarism, misappropriation of likeness, breach of confidence, or misappropriation or infringement of any intellectual property right, including patent, trademark, trade secret, trade dress and copyright;
- (g) arising out of or resulting from the rendering or failure to render any **Clinical Research Services or Healthcare Professional Services** by any **Insured** who is under the influence of alcohol, intoxicants, narcotics, abused prescription medication or prescription medication where treatment is counter-indicated, or hallucinogen;
- (h) arising out of or resulting from any guarantee or estimate of probable costs, or exceeding any cost estimate or guarantee;
- (i) arising out of or resulting from any claim, proceeding, investigation, order or regulation made by or on behalf of any governmental entity, provided, however, that this exclusion shall not apply to any such **Claim** brought by a governmental entity solely in its capacity as a customer or client of the **Insured** and which arises out of **Clinical Research Services** performed for such governmental entity by the **Insured** for a fee;

- (j) arising out of any actual, alleged or threatened failure to effect, maintain, procure or secure in whole or in part any license, order, permit or other contract or agreement that an **Insured** is obligated to maintain, procure or secure in connection with **Clinical Research Services**;
- (k) arising out of or resulting from the rendering or failure to render any professional services in the following areas:
 - (1) accounting;
 - (2) insurance;
 - (3) actuarial;
 - (4) legal;
 - (5) architectural and engineering; or
 - (6) surveying.

This exclusion applies regardless of whether a **Claim** or suit is brought by any client of an **Insured** or by any other person or organization, and regardless of whether any such professional services are usually provided as part of any **Insured's** profession.

2. Exclusions applicable to Insuring Agreements I.A.3, Products Liability and I.A.4, General Liability

The coverage under Insuring Agreements I.A.3 and I.A.4 of this **Policy** does not apply to **Damages** or **Claims Expenses** incurred with respect to any **Claim**:

- (a) for **Bodily Injury** arising out of the rendering or failure to render **Healthcare Professional Services** or **Clinical Research Services** by any person or organization;
- (b) for any malpractice, error, act or omission committed in the rendering of or failure to render **Healthcare Professional Services** or advice by any medical doctor, resident, intern or other person or organization under contract or agreement with the **Named Insured** to administer, oversee, direct, consult, advise or consult on or perform services for or in connection with a **Clinical Trial**;

but this exclusion does not apply to actions performed by the **Insured** in rendering, or failing to render, without remuneration, emergency treatment at the scene of an accident, medical crisis or disaster.

- (c) arising out of or resulting from **Personal Injury** or **Advertising Liability** resulting from the **Named Insured's Products**;

but this exclusion does not apply to **Bodily Injury**;

- (d) arising out of **Bodily Injury** or **Property Damage** resulting from the use of force expected or intended from the standpoint of the **Insured**;

but this exclusion does not apply to **Bodily Injury** resulting from the use of reasonable force to protect persons or property or from the expected or known side effects of a product in **Clinical Trials**;

- (e) arising out of the rendering of or failure to render **Clinical Research Services** or **Healthcare Professional Services** by any **Insured** or by any person or organization for whose acts or omissions the **Named Insured** is legally responsible;

- (f) arising out of loss of use of tangible property which has not been physically injured or destroyed, resulting from:

- (1) a delay in or lack of performance by or on behalf of the **Named Insured** of any contract or agreement; or

- (2) the failure of the **Named Insured's Products** or operations performed by or on behalf of the **Named Insured** to meet the level of performance, quality, fitness or durability warranted or represented by the **Named Insured**;

but this exclusion does not apply to loss of use of other tangible property resulting from the sudden and accidental physical injury to or destruction of the **Named Insured's Products** or **Named Insured's Operations** after such products or operations have been put to use by any person or organization other than an **Insured**;

- (g) arising out of **Property Damage** to the **Named Insured's Products**, or for the cost of inspecting, repairing or replacing any defective or allegedly defective product or part thereof or for loss of use of any defective or allegedly defective product;

- (h) arising out of **Property Damage** to work performed by or on behalf of the **Named Insured** arising out of the work or any portion thereof, or out of materials, parts or equipment furnished in connection therewith;

- (i) arising out of the withdrawal, recall, inspection, repair, replacement, or loss of use of the **Named Insured's Products** or **Named Insured's Operations** or of any property of which such products or operations form a

part, if such products, operations or property are withdrawn from the market or from use because of any known or suspected or alleged defect or deficiency therein;

- (j) arising out of or resulting from the manufacturing, handling, distribution, advertising, labeling, sale, application, ingestion, consumption, testing, exposure to or any use of any product or substance known as, made of or containing any one or more of the following:
 - (1) Diethylstilbestrol, or DES, or which has the same chemical formulary, or which is a stilbene derivative, or any other product or substance having substantially similar formulation, structure, or function by whatever name manufactured or marketed as DES;
 - (2) Ephedra, Ma huang, Ephedra sinica, Chinese Ephedra, ephedrine, pseudoephedrine, norpseudoephedrine, or any other product or substance having substantially similar formulation, structure or function, by whatever name manufactured, grown or marketed;
 - (3) Fenfluramine, Phentermine or Dexfenfluramine;
 - (4) Phenylpropanolamine, Phenylpropanolamine Hydrochloride, PPA or any product or drug containing any of these substances;
 - (5) any product containing silicone or similar which is in any form implanted or injected in the body; or
 - (6) tobacco or any tobacco products (or ingredients of, or used in the manufacture or production of, such products);
- (k) based upon or arising out of any of the **Named Insured's Products** sold in any country:
 - (1) before the **Named Insured's Products** have been approved for such sale; or
 - (2) after such **Named Insured's Products** have been declared unsafe; which is deemed in that country to be in violation of any statute, law, ordinance or regulation by the appropriate governmental authority having jurisdiction over such sale.
- (l) arising out of or resulting from any actual or threatened decision by any **Insured** not to provide or support the **Named Insured's Products** or **Named Insured's Operations**, or to cease such provision or support;

(m) arising out of **Bodily Injury, Personal Injury, Property Damage** or **Advertising Liability** for which the **Insured** or their indemnitee may be held liable:

- (1) as a person or organization engaged in the business of manufacturing, distributing, selling, or serving alcoholic beverages; or
- (2) if not so engaged, as an owner or lessor of premises used for such purposes, if such liability is imposed by, or because of the violation of, any statute, ordinance or regulation pertaining to the sale, gift, distribution or use of any alcoholic beverage;

(n) arising out of **Personal Injury** to:

- (1) any **Employee** or **Volunteer** of the **Named Insured** arising out of and in the course of his employment or retention by the **Named Insured**; or
- (2) the spouse, or any other relative of the **Employee** as a consequence of a claim under (n) (1) above.

This exclusion applies:

- (i) whether the **Insured** may be liable as an employer or in any other capacity; and
- (ii) to any obligation to share **Damages** with or repay someone else who must pay **Damages** arising out of such liability.

This exclusion does not apply to liability assumed by the **Named Insured** under an **Insured Contract**.

Voluntary participation as a **Patient** will not be deemed to be within the course of employment or performance of duties as described in paragraph (n) (1) above.

(o) arising out of **Property Damage** to:

- (1) property owned or alienated or occupied by or rented to the **Insured**, including any costs or expenses incurred by the **Insured**, or any other person or organization or entity, for repair, replacement, enhancement, restoration or maintenance of such property for any reason, including prevention of injury to a person or damage to another's property;
- (2) property used by the **Insured**; or

- (3) personal property in the care, custody or control of the **Insured** or as to which the **Insured** is for any purpose exercising physical control;
- (p) relating to **Advertising Liability** arising out of:
 - (1) failure of performance of contract;but this exclusion (p) (1) shall not apply to the unauthorized appropriation of ideas based upon alleged breach of an implied contract;
 - (2) infringement of patent, trademark, service mark, and trade name, other than titles or slogans by use thereof on or in connection with goods, products or services sold, offered for sale or advertised; or
 - (3) incorrect description or mistake in advertised price of goods, products or services sold, offered for sale or advertised;
- (q) arising out of or resulting from any action or omission that violates or is alleged to violate:
 - (1) the Telephone Consumer Protection Act (TCPA);
 - (2) the CAN-SPAM Act of 2003;
 - (3) the Fair Credit Reporting Act; or
 - (4) any statute, ordinance or regulation, other than TCPA, CAN-SPAM Act of 2003 or the Fair Credit Reporting Act, that prohibits or limits the sending, transmitting, communicating or distribution of material or information;
- (r) arising out of or resulting from the loss of, loss of use of, damage to, corruption of, inability to access, or inability to manipulate electronic data;

As used in this exclusion, electronic data means information, facts or programs stored as or on, created or used on, or transmitted to or from computer software, including systems and applications software, hard or floppy disks, CD-ROMS, tapes, drives, cells, data processing devices or any other media which are used with electronically controlled equipment;
- (s) arising out of or resulting from the unauthorized use of another's name or product in the **Insured's** e-mail address, domain name or metatag, or any other similar tactics to mislead another's potential customers;
- (t) arising out of or resulting from an electronic chatroom or bulletin board the **Insured** hosts, owns, or over which the **Insured** exercises control;

- (u) arising out of or resulting from **Advertising Liability** attributable to an **Insured** whose business is:
 - (1) advertising, broadcasting, publishing or telecasting;
 - (2) designing or determining content or web-sites for others; or
 - (3) an internet search, access, content or service provider.

The placing of frames, borders or links, or advertising, for the **Insured** or others anywhere on the Internet, is not, by itself, considered the business of advertising, broadcasting, publishing or telecasting;

- (v) arising out of or resulting from the failure of goods, products or services to conform with any statement of quality or performance made in the **Insured's** advertisement;
- (w) arising out of or resulting from oral or written publication of material, if done by or at the direction of the **Insured** with knowledge of its falsity;
- (x) caused by or at the direction of the **Insured** with the knowledge that the act would violate the rights of another and would inflict **Personal Injury** or **Advertising Liability**.

3. **Exclusions applicable to Insuring Agreements I.A.5, Clinical Trial Medical Expenses and I.A.6, Clinical Trial Medical Monitoring Expenses**

The coverage under Insuring Agreements I.A.5 or I.A.6 of this **Insurance** shall not apply to **Bodily Injury**:

- (a) to any **Insured**;
- (b) to a person hired to do work for or on behalf of the **Insured** or a tenant of the **Insured**;
- (c) to a person injured on that part of premises owned or rented by the **Insured** that the person normally occupies;
- (d) to a person, whether or not an **Employee** of any **Insured**, if benefits for the **Bodily Injury** are payable or must be provided under a workers' compensation or disability benefits law;
- (e) to a person injured while practicing, instructing or participating in any physical exercises or games, sports, or athletic contests;

- (f) excluded under Insuring Agreements I.A.3. or I.A.4., Products/Completed Operations and General Liability; or
- (g) to any prisoner.

4. Exclusions applicable to all Insuring Agreements

The coverage under each **Insuring Agreement** of this **Policy** does not apply to **Damages** or **Claims Expenses** incurred with respect to any **Claim**:

- (a) based upon or arising out of any actual alleged or threatened:
 - (1) burglary, inventory shortage or shrinkage, mysterious disappearance, robbery or theft;
 - (2) security breach of, unauthorized access to or unauthorized use of:
 - (i) the **Named Insured's Product**;
 - (ii) any property containing or incorporating the **Named Insured's Products**;
 - (iii) any property on which the **Named Insured's Operations** is or was performed;
 - (iv) any software, data or other information in electronic form; or
 - (v) any equipment, parts, programs or systems involving the use of computers, the Internet, or any networks or websites, or which are designed or used for the communication or information;

by any person or organization (including any **Insured**), regardless of whether this **Insurance** would otherwise apply to all or part of any such actual or alleged injury in the absence of any such actual, alleged or threatened breach, access or use;
- (b) for liability arising out of **Bodily Injury, Personal Injury** or **Property Damage** arising out of ownership, maintenance, operation, use, loading or unloading of:
 - (1) any **Automobile**, aircraft or watercraft owned or operated by or rented or loaned to any **Insured**; or

- (2) any other **Automobile**, aircraft or watercraft operated by any person in the course of his or her employment or volunteer duties for any **Insured**;

but this exclusion does not apply to loading or unloading of **Patients** from any **Automobile**, Aircraft or Watercraft equipped for transporting such **Patients** subject to the applicability of any other insurance.

- (c) arising out of **Bodily Injury** or **Property Damage** arising out of:
 - (1) the ownership, maintenance, operation, use, loading or unloading of any **Mobile Equipment** while being used in any prearranged or organized racing, speed or demolition contest or in any stunting activity or in practice or preparation for such contest or activity; or
 - (2) the operation or use of any snowmobile, motorcycle, moped or motorized bicycle, or trailer designed for use therewith;
- (d) for **Bodily Injury** or **Property Damage** arising out of and in the course of the transportation of **Mobile Equipment** by any **Automobile** owned or operated by or rented or loaned to any **Insured**;
- (e) associated with implementation of any compliance program or any policies, procedures or practices relating to participation as a provider of medical services to a managed care organization or under a healthcare benefit program, whether initiated voluntarily or pursuant to direction by, order of, or in settlement with a government body, hospital, healthcare facility or managed care organization;
- (f) arising out of or resulting from:
 - (1) any conduct, physical act, gesture, or spoken or written words of a sexual or physically violent nature by any **Insured**, including sexual intimacy (whether or not consensual), sexual molestation, sexual act, sexual contact, sexual advances, requests for sexual favors, sexual or physical assault or battery, sexual or physical abuse, sexual harassment or exploitation, or other verbal or physical conduct of a sexual nature; or
 - (2) the **Insured's** actual or alleged negligent employment, investigation, supervision, hiring, training or retention of any **Employee, Insured** or person for whom the **Insured** is legally responsible and whose conduct falls within paragraph (1) above;
- (g) arising from costs of complying with physical modifications to any premises or any changes to the **Insured's** usual business operations mandated by the Americans with Disabilities Act of 1990;

- (h) based upon or arising out of any action or proceeding brought by or on behalf of any federal, state or local governmental, regulatory or administrative agency, regardless of the name in which such action or proceeding is brought, including the Health Insurance Portability and Accountability Act of 1996, and the Social Security Act, 42 U.S.C. §1320a, et. seq.;
- (i) by any person or organization or governmental entity, including any supplier, or third-party payor, alleging or arising out of:
 - (1) improper, excessive or unnecessary billing for the cost of the **Insured's** goods or services; or
 - (2) failure of the **Insured** to pay for the cost of goods or services furnished to the **Insured**;
- (j) arising out of failure to pay any bond, interest on any bond, any debt, financial guarantee or debenture;
- (k) arising out of any financial or investment advice given, referrals, warranties, guarantees, or predictions of future performance made by any **Insured** as regards specific and identifiable investment items including personal property, real property, stocks, bonds or securities;
- (l) made by or against or in connection with any business enterprise not named in the Declarations (including the ownership, maintenance or care of any property in connection therewith), which is owned by any **Insured** or in which any **Insured** is a trustee, partner, officer, director or **Employee**;
- (m) arising out of the Employee Retirement Income Security Act of 1974;
- (n) or **Circumstance** in respect of which any **Insured** has given notice to any insurer of any other policy or for which there was self-insurance in force prior to the Inception Date of this **Policy**;
- (o) or **Circumstance** known to any **Insured** prior to the Inception Date and not disclosed to the Underwriters by the Inception Date;
- (p) or **Circumstance** arising out of any negligent act, error or omission which first took place, or is alleged to have taken place, prior to the Retroactive Date;
- (q) arising out of discrimination including discriminatory employment practices, allegations of actual or alleged violations of civil rights or acts of discrimination based entirely or in part on race, gender, pregnancy, national origin, religion, age or sexual orientation;

but this exclusion shall not apply to the selection of candidates for a human **Clinical Trial**;

- (r) directly or indirectly arising out of:
 - (1) the actual, alleged or threatened discharge, dispersal, release or escape or failure to detect the presence of **Pollutants**, provided, however, that this exclusion shall not apply to: (i) **Personal Injury** sustained by any **Patient**, visitor or invitee; and (ii) **Personal Injury** or **Property Damage** arising out of heat, smoke or fumes from a **Hostile Fire**;
 - (2) the manufacture, distribution, sale, resale, rebranding, installation, repair, removal, encapsulation, abatement, replacement or handling of, exposure to or testing for **Pollutants** contained in a product, carried on clothing, inhaled, transmitted in any fashion or found in any form whatsoever; or
 - (3) any governmental or regulatory directive or request that the **Insured** or anyone acting under its direction or control to test for, monitor, clean up, remove, contain, treat, detoxify or neutralize said **Pollutants**;
- (s) arising out of the insolvency or bankruptcy of any **Insured** or of any other entity including the failure, inability, or unwillingness to pay **Claims**, losses or benefits due to the insolvency, liquidation or bankruptcy of any such individual entity;
- (t) for fines, sanctions, taxes or penalties, punitive, multiplied or exemplary sums or the return of or the voluntary or involuntary reimbursement for fees, costs or expenses charged by any **Insured** whether by offset or otherwise;
- (u) arising out of **Bodily Injury** or **Personal Injury** to any **Employee** or **Volunteer** of the **Insured** arising out of and in the course of his employment by the **Insured**, or under any obligation for which the **Insured** or any carrier as his insurer may be liable, under any Workers' Compensation, Unemployment Compensation, or Disability Benefits Law;
- (v) based upon or arising out of a violation or alleged violation of the Securities Act of 1933, or the Securities Exchange Act of 1934 as amended, or any State Blue Sky or securities law;
- (w) or actual or alleged violation of the Racketeer Influenced and Corrupt Organizations Act, 18 U.S.C. §1961 et seq.;

- (x) based upon or arising out of any actual or alleged unfair or deceptive trade practice or violation of any federal, state, or local anti-trust, restraint of trade, unfair competition, or price fixing law, or consumer protection legislation;
- (y) caused directly or indirectly, in whole or in part, by:
 - (1) any fungus(es) or spore(s);
 - (2) any substance, vapor or gas produced by or arising out of any fungus(es) or spore(s); or
 - (3) any materials, product, building component, building or structure that contains, harbors, nurtures or acts as a medium for any fungus(es) or spore(s);

regardless of any other cause, event, material, product and/or building component that contributed concurrently or in any sequence to that injury or **Damages**.

For the purposes of this exclusion:

“Fungus(es)” includes any form of mold, mushroom or mildew.

“Spore(s)” means any reproductive body produced by or arising out of any fungus(es).

This exclusion shall not apply to **Claims** arising from **Clinical Research Services** that would otherwise be covered hereunder.

- (z) based upon or arising out of any **Insured’s** data processing services, including:
 - (1) conversion of data from source material into media for processing on the **Insured’s** electronic data processing system;
 - (2) processing of data by the **Insured** on the **Insured’s** electronic data processing system; or
 - (3) design or formulation of an electronic data processing program or system;
- (aa) arising out of any **Named Insured’s Products** manufactured, handled, sold or distributed in knowing or willful violation of any federal or state law, statute, ordinance or regulation;
- (ab) based upon or arising out of any **Insured** gaining any profit, remuneration or advantage to which such **Insured** was not legally entitled;

- (ac) against any subsidiary designated as an Additional Insured in Item 10 of the Declarations or its past, present, or future employees, directors, officers, trustees, review board or committee members, or volunteers acting in their capacity as such, which are based upon, arise out of, directly or indirectly result from, are in consequence of, or in any way involve any fact, circumstance, situation, transaction, event, **Accident**, or acts, errors or omissions or series of facts, circumstances, situations, transactions, events, **Accidents** or negligent acts, errors or omissions happening before the date such entity became a subsidiary or after the date it ceased to be a subsidiary;
- (ad) relating to or arising out of asbestos, silica or lead;
- (ae) based upon, arising out of, or resulting from any actual or alleged: (1) failure to obtain, effect, or maintain any form, policy, plan or program of insurance, stop loss or provide excess coverage, reinsurance, self-insurance, suretyship, or bond; (2) commingling, mishandling of or liability to pay, collect or safeguard funds; or (3) failure to collect or pay premiums, commissions, brokerage charges, fees or taxes;
- (af) arising out of or resulting from war, whether or not declared, civil war, insurrection, rebellion or revolution or to any act or condition incidental to any of the foregoing;
- (ag) arising out of or relating to any loss, damage, or cost or expense of whatsoever nature directly or indirectly caused by, resulting from happening through, arising out of or in connection with any **Act of Terrorism**, regardless of any other cause contributing concurrently or in any other sequence to the loss, damage, cost or expense;

“**Act of Terrorism**” means an act or threat of violence or an act harmful to human life, tangible or intangible property or infrastructure with the intention or effect to influence any government or to put the public or any section of the public in fear. In any action, suit or other proceedings where the Underwriters allege that by reason of this exclusion, a loss, damage, cost or expense is not covered by this **Policy**, the burden of proving that such loss, damage, cost or expense is covered shall be upon the **Insured**;

- (ah) brought against any **Insured** by another **Insured** hereunder;

but this exclusion shall not apply to **Bodily Injury** sustained by any **Patient** as a recipient of **Clinical Research Services** or **Healthcare Professional Services** rendered, or failing to be rendered, by any other **Insured**;

- (ai) arising out of or resulting from the existence, emission or discharge of any electromagnetic field, electromagnetic radiation or electromagnetism that

actually or allegedly affects the health, safety or condition of any person, or the environment, or that affects the value, marketability, condition or size of any property;

(aj) arising out of a **Wrongful Act**;

“Wrongful Act” means any actual or alleged negligent act, error, omission, misstatement, misleading statement, neglect or breach of duty by the **Directors or Officers**, individually or collectively, in the discharge of their duties solely in their capacity as Directors or Officers of the **Named Insured**;

“Directors or Officers” means any partner, executive officer, hospital administrator, member of a **Named Insured** which is a not-for-profit corporation, stockholder or member of the board of directors, trustees or governors of the **Named Insured**;

(ak) arising out of or relating to any liability under any contract or agreement, whether written or oral, unless:

(1) such liability would have attached to the **Insured** in the absence of such contract or agreement; or

(2) such liability has been assumed under an **Insured Contract**;

but this exclusion does not apply to liability assumed in a written contract or agreement with a subcontractor as covered under Clause II. Insureds, (a) (3), (4) or (5);

(al) related to any **Clinical Trial** if:

(1) such **Claim** arises out of any exposure to **Biologics, Pharmaceuticals, Nutraceuticals, Medical Devices** or any other product or procedure, upon or within human beings, during the **Clinical Trial** unless the exposure has been approved by the governmental or regulatory authority having jurisdiction over the **Clinical Trial**; or

(2) the act, error or omission takes place after any governmental or regulatory authority having jurisdiction over the **Clinical Trial**:

(i) places or imposes a hold on the **Clinical Trial**;

(ii) withdraws approval of an Investigational New Drug Application, Investigational Device Exception Application or similar authorization applicable to the **Clinical Trial**; or

- (iii) directs or orders that the **Clinical Trial** be discontinued.

V. DEFINITIONS

Wherever used in this **Policy**, the bolded terms have the meaning set out below:

- (a) “**Accident**” means an event or happening, including continuous or repeated exposure to substantially the same general harmful conditions, which results in **Bodily Injury, Personal Injury, Property Damage, or Advertising Liability** to one or more persons or entities.
- (b) “**Advertising Liability**” means injury arising out of one or more of the following, committed in the course of the **Insured’s** advertising activities:
 - (1) libel, slander or defamation;
 - (2) infringement of copyright, title, slogan, trade dress, or advertising idea;
 - (3) piracy or idea misappropriation under an implied contract; or
 - (4) invasion of right of privacy, subject always to exclusion IV.4.h.
- (c) “**Automobile**” means a land motor vehicle, trailer or semi-trailer designed for travel on public roads (including any machinery or apparatus attached thereto), but does not include **Mobile Equipment**.
- (d) “**Biologic**” means any substance or product consisting of or originally derived from a living organism or its by-products (including globulin, serum, blood or blood components, vaccine, protein, antibody, antigen or analogous product) administered orally, topically, or via injection and used in the diagnosis, prevention, mitigation, or treatment of illness or disease.
- (e) “**Bodily Injury**” means physical injury (including death at any time resulting therefrom), mental injury, mental illness, mental anguish, humiliation, emotional upset, shock, sickness, disease or disability.
- (f) “**Circumstance**” means:
 - (1) a negligent act, error or omission;
 - (2) an **Accident**;
 - (3) the suspension of a **Clinical Trial** for:

- (i) safety reasons; or
 - (ii) non-compliance with the trial protocol, where there is a reasonable probability that non-compliance would place a **Patient** at increased risk of **Bodily Injury**; or
- (4) an adverse event concerning the **Named Insured's Product** or the **Named Insured's Operations** if:
- (i) the adverse event has been reported to, or was required to be reported to, the United States Food and Drug Administration or other appropriate governmental authority; or
 - (ii) it is known or suspected to have resulted in a serious adverse outcome in a person or **Patient**, including death or substantial risk of death, hospitalization, disability or permanent impairment or damage, congenital anomaly or birth defect, required medical or surgical intervention to prevent further injury, or jeopardy to the **Patient** to the extent that medical or surgical intervention may be necessary in the future;

which in the opinion of the **Insured** (acting reasonably) could lead to a **Claim**.

- (g) "**Claim**" means a written demand of an intention to hold the **Insured** responsible for **Damages**, including the service of suit or the institution of arbitration or mediation proceedings.
- (h) "**Claims Expenses**" means:
 - (1) reasonable and customary fees charged by an attorney who is designated and agreed in advance by the Underwriters in consultation with the **Insured**, but subject always to the Underwriters' final decision; and
 - (2) all other fees, costs and expenses resulting from the investigation, adjustment, defense and appeal or a **Claim**, if incurred by the Underwriters, or by the **Insured** with the written consent of the Underwriters.

Claims Expenses does not include any salary, overhead or other charges by the **Insured** for any time spent in co-operating in the defense and investigation of any **Claim** or **Circumstance** notified under this **Insurance**.

- (i) **“Clinical Research Services”** means those services performed or advice given by the **Named Insured**, or another **Insured** on the **Named Insured’s** behalf, for a fee or other remuneration, in connection with clinical or laboratory research and development of **Biologics, Pharmaceuticals, Nutraceuticals** or **Medical Devices** performed in connection with a **Clinical Trial**. **Clinical Research Services** does not include **Healthcare Professional Services**.
- (j) **“Clinical Trial”** means an organized study sponsored, investigated or conducted by the **Named Insured** that adheres to an **Institutional Review Board**-approved written protocol and which provides clinical data for the assessment of the effects of the **Biologics, Pharmaceuticals, Nutraceuticals** or **Medical Devices** via their testing to establish their effectiveness, bioequivalence or safety.
- (k) **“Clinical Trial Medical Expenses”** means reasonable expenses for:
 - (1) first aid administered at the time of an accident;
 - (2) necessary medical, surgical, x-ray and dental services, including prosthetic devices; and
 - (3) necessary ambulance, hospital, professional nursing and funeral services.
- (l) **“Clinical Trial Medical Monitoring Expenses”** means expenses properly incurred in the medical testing on or medical monitoring of a claimant in the absence of physical injury, illness or disease, arising out of his participation in a **Clinical Trial**, and does not include any sums incurred for the planned, current treatment of side effects identified in the relevant clinical trial protocol.
- (m) **“Damages”** means a civil monetary judgment, award or settlement but does not include:
 - (1) the restitution of compensation and expenses paid to the **Insured** for services and goods;
 - (2) the voluntary or involuntary return or offset of fees, charges, or commissions for goods or services already provided or contracted to be provided;
 - (3) future royalties or future profits, the voluntary or involuntary disgorgement of profits by an **Insured**, or the costs of complying with orders granting injunctive or equitable relief;

- (4) judgments or awards deemed uninsurable by law; or
 - (5) any amounts for which the **Insured** is not found financially liable or legally obligated to pay.
- (n) **“Employee”** means a person on the **Insured’s** regular payroll, with federal and, if applicable, state taxes withheld, whose work is directed or controlled by the **Insured**, including part-time and seasonal **Employees** and leased workers. **Employee** does not include a temporary worker.
- (o) **“Extended Reporting Period”**, if applicable, means the period of time after the end of the **Policy Period** for reporting **Claims** as set out in Condition IX.
- (p) **“Healthcare Professional Services”** means services performed by an **Insured** in the treatment and/or care of any **Patient**, including:
- (1) health care, medical care, diagnostic, laboratory, x-ray or other health care treatment services including any of the following services: (i) medical, (ii) surgical, (iii) dental, (iv) psychiatric, (v) radiological, (vi) mental health, (vii) chiropractic, (viii) osteopathic and (ix) nursing;
 - (2) the furnishing or dispensing of medications, drugs, blood, blood products, tests or medical, surgical, dental, or psychiatric supplies, equipment, devices or appliances in connection with such care;
 - (3) the furnishing of food or beverages in connection with such care; and
 - (4) the handling of or the performance of post-mortem examinations on human bodies.
- (q) **“Hostile Fire”** means a fire which becomes uncontrollable or breaks out from where it was intended to be.
- (r) **“Institutional Review Board”** means:
- (1) a board, committee, group or similar organization; or
 - (2) an ethics committee;
- designated, directed or requested by an institution or other person or organization to review a **Clinical Trial** including any:
- (i) approval; or
 - (ii) periodic review;

of any such **Clinical Trial**.

- (s) **“Insured Contract”** means that part of any written and signed contract or agreement pertaining to the **Named Insured’s** business under which any **Insured** assumes the tort liability of any another party to pay for **Bodily Injury** or **Property Damage** to a third person or organization. Tort liability means a liability that would be imposed by law in the absence of any contract or agreement.
- (t) **“Local Admitted Policy”** means any policy issued in a jurisdiction outside of the United States, its territories or Puerto Rico, or Canada, that provides required coverage in such jurisdiction for any **Damages** or **Claim Expenses** that would otherwise be covered under the terms and conditions of this **Policy**.
- (u) **“Medical Device”** means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent or other similar or related article, component part or accessory that is:
 - (1) subject to United States Food and Drug Administration regulation or the equivalent of such regulations in any foreign jurisdiction;
 - (2) intended for use in the diagnosis, cure, mitigation, treatment or prevention of injury, sickness or disease in humans; or
 - (3) intended to affect the structure or any function of the human body;that does not achieve its primary intended purposes through chemical or biological action within or upon the human body and which is not dependent upon being metabolized for the achievement of its primary intended purposes.
- (v) **“Nutraceutical”** means a dietary supplement as defined by the United States Dietary Supplement Health and Education Act, whether intended for ingestion or topical application.
- (w) **“Mobile Equipment”** means a land vehicle (including any attached machinery or apparatus) whether or not self-propelled:
 - (1) not subject to motor vehicle registration;
 - (2) maintained for use exclusively on premises owned by or rented to the **Named Insured**, including the ways immediately adjoining;
 - (3) designed for use principally off public roads; or

- (4) designed or maintained for the sole purpose of affording mobility to equipment of the following types forming an integral part of or permanently attached to such vehicle:
- (i) power cranes, shovels, loaders, diggers and drills;
 - (ii) concrete mixers (other than the mix-in-transit type), graders, scrapers, rollers and on the road construction or repair equipment;
 - (iii) air-compressors, pumps and generators including spraying, welding and building cleaning equipment; or
 - (iv) geophysical exploration and well servicing equipment.
- (x) **“Named Insured”** means the entity or person identified in Item 1 of the Declarations.
- (y) **“Named Insured’s Products”** means any goods or products manufactured, developed, designed, created, tested, leased, licensed, rented, sold, handled, disposed of or distributed by the **Named Insured** or by others trading under its name, including:
- (1) **Biologics**;
 - (2) **Pharmaceuticals**;
 - (3) **Nutraceuticals**;
 - (4) **Medical Devices**; and
 - (5) products that are used, or are intended for use in **Clinical Trials**, or the providing of **Clinical Research Services**;

including any container thereof (other than a vehicle) but shall not include a vending machine or any property, other than such container rented to or located for use of others but not sold.

Named Insured’s Products includes:

- (i) warranties or representations made at any time with respect to the fitness, quality, durability, performance, use, handling, operation or safety of the **Named Insured’s Products**;

- (ii) advice or demonstration of procedures for the use of the **Named Insured's Product** by the **Named Insured** or any other **Insured** on behalf of the **Named Insured**;
- (iii) the providing of or failure to provide warnings or instructions; and
- (iv) the "emergency use", "compassionate use", "treatment use" or "continued access" as those terms are defined by the United States Food and Drug Administration ("FDA") or corresponding foreign regulatory body of the **Named Insured's Pharmaceuticals, Biologics or Medical Devices** in connection with the **Named Insured's Clinical Trials** provided such **Pharmaceuticals, Biologics or Medical Devices** are provided and administered in accordance with strict adherence to the FDA's or corresponding foreign regulatory body's regulations and procedures for such use and, where required, prior approval for such use has been obtained from the FDA or applicable corresponding foreign regulatory body.

(z) **"Named Insured's Operations"** means:

- (1) work, operations or services performed by the **Insured** or on the **Named Insured's** behalf including testing, review, installation, maintenance, or repair of the **Named Insured's Product**;
- (2) materials, parts or equipment furnished in connection with such work, operations or services.

Named Insured's Operations includes:

- (i) warranties or representations made at any time with respect to the fitness, quality, durability, performance, use, handling, operation, safety or maintenance of the **Named Insured's Operations**; and
- (ii) the providing of or failure to provide warnings or instructions.

(aa) **"Patient"** means a human being who is or becomes a participant in a **Clinical Trial**, either as a recipient of the test article or as a control, or as a **Volunteer** participating in a **Clinical Trial**.

(bb) **"Personal Injury"** means:

- (1) **Bodily Injury**;
- (2) false arrest, false imprisonment, wrongful eviction, detention or malicious prosecution;

- (3) libel, slander, defamation of character or invasion of right of privacy, unless arising out of any advertising activities; or
 - (4) wrongful eviction from, wrongful entry into, or invasion of the right of private occupancy of a room, dwelling or premises that a person occupies, committed by or on behalf of its owner, landlord or lessor.
- (cc) **“Pharmaceutical”** means any synthetic or natural chemical, other than a **Biologic**, administered orally, topically or via injection, to treat, diagnose, cure, mitigate or prevent sickness or disease, and is:
- (1) subject to United States Food and Drug Administration regulation or the equivalent of such regulations in any foreign jurisdiction; and
 - (2) intended for use in the diagnosis, cure, mitigation, treatment or prevention of injury, sickness or disease in humans.
- (dd) **“Policy”, “Insurance Policy” or “Insurance”** mean this contract of insurance including the application, any Declarations, and any endorsements or variations, all forming part hereof.
- (ee) **“Policy Period”** means the period of time between the Inception Date and the Expiration Date unless terminated earlier, and specifically excludes any **Extended Reporting Period**.
- (ff) **“Pollutants”** means any solid, liquid, gaseous or thermal irritant or contaminant, including asbestos and/or lead (or products containing asbestos and/or lead whether or not the asbestos and/or lead is or was at any time airborne as a fiber or particle, contained in a product, carried on clothing, inhaled, transmitted in any fashion or found in any form whatsoever), smoke, vapor, soot fumes, acids, alkalis, toxic chemicals or waste (waste includes materials to be recycled, reconditioned or reclaimed).
- (gg) **“Principal Investigator”** means the individual, or in the case of an investigation by a team of individuals, the leader of that team, who is responsible for ensuring that the **Clinical Trial** is conducted in accordance with the relevant investigator statement, investigational plan, the written protocol and regulations for protecting the rights, safety and welfare of the **Patients** under such investigator’s care.
- (hh) **“Products/Completed Operations Liability Hazard”** means **Bodily Injury** or **Property Damage** which arises out of the **Named Insured’s Products**, or **Named Insured’s Operations**, or reliance upon a representation or warranty made at any time with respect thereto, but only

if that **Bodily Injury** or **Property Damage** occurs away from the premises owned by or rented to the **Insured**, and takes place:

- (1) after physical possession of such **Named Insured's Products** has been relinquished to others; or
- (2) after such **Named Insured's Operations** have been completed or abandoned.

Named Insured's Operations shall be deemed completed at the earliest of the following times:

- (i) when all operations to be performed by or on behalf of the **Named Insured** under the contract have been completed;
- (ii) when all operations to be performed by or on behalf of the **Named Insured** at the site of the operations have been completed; or
- (iii) when the portion of the work out of which the **Bodily Injury** or **Property Damage** arises has been put to its intended use by any person or organization other than another contractor or subcontractor engaged in performing operations for a principal as a part of the same project.

Named Insured's Operations which may require further service or maintenance work, or correction, repair or replacement because of any defect or deficiency, but which are otherwise completed, shall be deemed completed.

Products/Completed Operations Liability Hazard does not include **Bodily Injury** or **Property Damage** arising out of:

- (a) the transportation of property, unless the injury or damage arises out of a condition in or on a vehicle not owned or operated by the **Named Insured**, and that condition was created by the loading or unloading of that vehicle by any **Insured**; or
- (b) the existence of tools, uninstalled equipment or abandoned or unused materials.

(ii) "**Property Damage**" means:

- (1) physical injury to or destruction of tangible property, including consequential loss of use thereof; or

- (2) loss of use of tangible property which has not been physically injured or destroyed.
- (jj) “**Volunteer**” means a person who is not an **Employee**, and who donates his work and acts at the direction of and within the scope of duties determined by the **Named Insured**, and is not paid a fee, salary or other compensation by either the **Named Insured** or anyone else for their work performed by or on behalf of the **Named Insured**.

Further, throughout this **Policy**:

- A. The singular includes the plural and vice versa, and the masculine includes the feminine;
- B. “Including” and “include(s)” mean without limitation;
- C. Any right, obligation or sum payable shall in every case be subject to the terms, conditions, limitations and exclusions of this **Policy** including the Limits of Liability and Deductible specified in Items 3 and 4 respectively of the Declarations.
- D. Any reference to legislation shall include any similar or related federal, state or local law, ordinance or regulation, any amendments, and any rules or regulations promulgated thereunder or by agencies or similar bodies thereof;
- E. Any reference to a regulatory or investigative or other federal, state or local governmental body shall include any similar or related agency or body;
- F. Any requirement for notification or payment to the Underwriters under this **Policy** shall be discharged if sent by prepaid express courier or certified mail, or fax or email (if received and there capable of being easily read), to the entity named in Item 8 of the Declarations, or other designated address) except in respect of **Claims** or **Circumstances**, which shall be sent to the entity named in Item 9 of the Declarations;
- G. The descriptions in the headings and subheadings of this **Policy** are solely for convenience, and form no part of the terms and conditions of coverage; and
- H. All or part of any provision of this **Policy** which is or becomes void or illegal, invalid or unenforceable by a court or other competent body under the law of any applicable jurisdiction shall be deleted. The parties shall use all reasonable efforts to agree a replacement for the provision deleted

which achieves as far as possible the same effect as would have been achieved by the deleted provision had it remained enforceable.

VI. LIMITS OF LIABILITY

A. Subject to clause XVII each of the Limits of Liability stated in Items 3(a) – (d) of the Declarations as the limit for "Each **Claim**" is the most the Underwriters will pay in respect of each of Insuring Agreements I.A.1-4. purchased and in force:

- i) for all **Damages** and **Claims Expenses** arising out of the same, related, or continuing **Accidents** without regard to the number of **Insureds, Claims** or claimants; and
- ii) for all **Damages** and **Claims Expenses** arising out of the same related or continuing negligent acts, errors or omissions without regard to the number of **Insureds, Claims** or claimants.

B. The Limit of Liability stated in Item 3(e) of the Declarations as "Term Aggregate" is the most the Underwriters will pay for all **Damages** and **Claims Expenses** arising out of all **Claims** which are covered under the terms and conditions of this **Policy**.

C. The Each **Claim – Clinical Trial Medical Expenses Sublimit**" stated in Item 3(f) of the Declarations is the most the Underwriters will pay for any one claimant for **Clinical Trial Medical Expenses**.

The "Term Aggregate – **Clinical Trial Medical Expenses Sublimit**" stated in Item 3(g) of the Declarations is the most the Underwriters will pay for all **Clinical Trial Medical Expenses**.

These Sublimits are part of and not in addition to the Limit of Liability stated in Item 3(e) of the Declarations.

D. The Each **Claim – Clinical Trial Medical Monitoring Expenses Sublimit**" stated in Item 3(h) of the Declarations is the most the Underwriters will pay for any one claimant for **Clinical Trial Medical Monitoring Expenses**.

The "Term Aggregate – **Clinical Trial Medical Monitoring Expenses Sublimit**" stated in Item 3(i) of the Declarations is the most the Underwriters will pay for all **Clinical Trial Medical Monitoring Expenses**.

These Sublimits are part of and not in addition to the Limits of Liability stated in Item 3(e) of the Declarations.

VII. DEDUCTIBLE

The Deductible amount set out in Item 4 of the Declarations shall be satisfied by payments by the **Insured** of **Damages** and/or **Claims Expenses** resulting from each **Claim** first made to the Underwriters during the **Policy Period** and/or any applicable **Extended Reporting Period** as a condition precedent to the payment by the Underwriters of any amounts due hereunder. The Underwriters shall be liable only for the amounts in excess of such Deductible subject to the Underwriters' Limits of Liability. The Deductible is in addition to the Underwriters' Limits of Liability and not part thereof, and this **Policy** sits in excess thereof. The **Insured** shall make direct payments within the Deductible to appropriate parties designated by the Underwriters. The Deductible is to be uninsured, unless otherwise agreed by the Underwriters. Under no circumstances shall the Underwriters be called upon to pay the Deductible, but the Underwriters may do so at their sole discretion. Such payment shall in no way affect the Underwriters' ability to collect the Deductible from the **Insured**. The existence of "other insurance" shall not affect or abrogate the obligation of the **Insured** to pay the Deductible as required.

The Each **Claim** Deductible amount is waived to the extent of and by the amount of any payment of **Damages** and/or **Claim Expenses** paid in connection with such **Claim** by any **Local Admitted Policy**.

VIII. INNOCENT INSURED

Whenever coverage under this **Insurance** would be excluded, suspended or lost owing to:

- A. the application of exclusion IV.1.(c) or IV.2.(d) relating to intentional, criminal, dishonest, fraudulent or malicious acts, errors or omissions by any **Insured**; or
- B. non-compliance with any condition relating to the giving of notice to the Underwriters where an **Insured** is in default solely as a result of the failure of another **Insured** so to comply;

such insurance coverage as would otherwise be afforded under this **Policy** shall remain in effect with respect to those **Insureds** who did not personally participate in, or acquiesce in or remain passive after having personal knowledge of, (a) one or more of the acts, errors or omissions described in any such exclusion, or (b) such failure to give notice;

provided that after becoming aware of such act, error or omission or **Accident** or any failure to give notice, an **Insured** seeking the benefit of this clause shall inform the Underwriters immediately in writing of such event.

IX. EXTENDED REPORTING PERIOD

- A. In the event of cancellation or non-renewal of this **Insurance** by the Underwriters, the **Named Insured** may request an **Extended Reporting Period** (applicable to all Insuring Agreements already purchased and in force) in which to report a **Claim** otherwise covered by this **Insurance**. Such request must be made by the **Named Insured** in writing and received by the Underwriters within sixty (60) days of the effective date of such cancellation or non-renewal and the **Extended Reporting Period** will replace the period of 60 days of grace provided to the **Named Insured** under XI. E. below.

The Underwriters shall then provide an **Extended Reporting Period** to the **Named Insured** for 12 months commencing at such cancellation or non-renewal. An additional, fully earned premium of 150% of the premium payable for this **Insurance** shall be payable within 30 days of such request. Following such payment the **Extended Reporting Period** is non-cancelable.

All **Claims** first made during the **Extended Reporting Period** shall be deemed to have been made on the last day this **Insurance** was in effect and must be reported in writing to the Underwriters prior to the expiration of the **Extended Reporting Period**.

No **Named Insured** shall have the right to purchase any **Extended Reporting Period** for any of the Insuring Agreements A. 1-6. already purchased and in force, independently of any other **Extended Reporting Period**.

- B. The Limit of Liability for the **Extended Reporting Period** shall be part of, and not in addition to, the Underwriters' Limit of Liability for the **Policy Period**. Such Limit of Liability may have been reduced or exhausted by indemnity payments or payments for **Claims Expenses** from previous **Claims**.
- C. The quotation by the Underwriters of a different premium or Deductible or Limit of Liability or changes in **Policy** language for the purpose of renewal shall not constitute a refusal to renew by the Underwriters.
- D. The right to the **Extended Reporting Period** shall not be available to the **Named Insured** where cancellation or non-renewal by the Underwriters of the **Policy** is due to non-payment of premium or failure of an **Insured** to pay such amounts in excess of the applicable Limit of Liability or within the applicable Deductible, or any material breach of this **Policy**.
- E. All notices and premium payments with respect to the **Extended Reporting Period** shall be directed to the Underwriters through the entity named in Item 8 of the Declarations.

X. OTHER INSURANCE

If the **Insured** has insurance provided by other insurers against a **Claim** covered by this **Insurance**, the Underwriters shall not be liable under this **Insurance** for a greater proportion of such **Claim** and **Claim Expenses** than the applicable Limit of Liability bears to the total applicable limit of liability of all valid and collectible insurance against such **Claim**, provided, however, that if the **Insured** has insurance provided by other insurers whose insurance is stated as excess over any other insurance available to the **Insured**, this **Insurance** shall also apply solely in excess of such insurance, unless such other insurance is written only and identified as specific excess over the Limit of Liability of this **Insurance**.

However, if any **Damages** and/or **Claim Expenses** resulting from any **Claim** are also insured under any **Local Admitted Policy**, this **Policy** shall apply in accordance with this **Policy's** terms and conditions, as specific excess over such **Local Admitted Policy**, with the **Local Admitted Policy** applying as specific primary coverage whether the **Local Admitted Policy** is stated to be primary, contributory, excess, contingent or otherwise.

Under no circumstances shall any portion of this **Policy's** Limit of Liability be available to pay **Damages** and/or **Claim Expenses** until all of such **Local Admitted Policy's** Limit of Liability has been exhausted.

If there is any other such insurance at the time of any event giving rise to a **Claim** under this **Policy** the **Insured** shall promptly provide the Underwriters in writing with full details of such other insurance, including the identity of the insurer and the policy number, and such further information as the Underwriters may reasonably require.

XI. NOTICE OF CLAIM, OR CIRCUMSTANCE THAT MIGHT LEAD TO A CLAIM

- A. If during the **Policy Period** any **Claim** is made against the **Insured** or the **Insured** becomes aware of a **Circumstance**, the **Insured** shall as soon as practicable notify the Underwriters thereof in writing through the persons named in Item 9 of the Declarations and forward to them every demand, notice, summons or other process received by the **Insured** or its representative. The **Insured's** duty to provide notice in accordance with this provision is a condition precedent to coverage and the Underwriters shall not be subject to any liability under this **Policy** if the **Insured** fails to comply in full with this Condition XI.
- B. Any such notice in respect of a **Circumstance** to the extent possible must include details of:

- (1) the specific negligent act, error, or omission, **Accident**, suspension of a **Clinical Trial** or adverse event;
- (2) the injury or damage which may result or has resulted from the negligent act, error, or omission, **Accident**, suspension of a **Clinical Trial** or adverse event; and
- (3) the circumstances by which the **Insured** first became aware of the negligent act, error or omission, **Accident**, suspension of a **Clinical Trial** or adverse event.

C. A **Claim** will be deemed to have been made at the earlier of the following times:

- (1) when the Chief Executive Officer, Chief Financial Officer, Chief Risk Officer, Head of Compliance, General Counsel or any member of the **Named Insured's** legal or risk management department or any other person responsible for its insurance administration first receives written notice of such **Claim**; or
- (2) when the Underwriters receive written notice of such **Claim** through the persons named in Item 9 of the Declarations.

D.

- (1) All Claims arising out of the same, continuing or related negligent act, error or omission or arising out of the same, continuing or related **Accident** or which are the subject of the written notice under XI. B. shall be considered one **Claim** and deemed to have been made at the time of such notice or the first of the related **Claims** if:
 - (i) the negligent act, error or omission or **Accident** which causes or is alleged to cause injury or damage affects two or more persons and is attributable to a single, direct cause;
 - (ii) the first relevant negligent act, error or omission or **Accident** occurs after the Retroactive Date and before the Expiration Date of the **Policy Period**;
 - (iii) the first of all such related **Claims**:
 - (a) has been made within the **Policy Period**; or
 - (b) directly relates to a **Circumstance** notified within the **Policy Period**; and

- (iv) the **Named Insured** has requested in writing prior to, or within 120 days after, the Expiration Date of the **Policy Period** that the Underwriters agree to such designation as one **Claim**, such consent not to be unreasonably withheld.
- (2) If the Underwriters agree to designate such **Claims** (falling within D. (1) above or within I.A.3. (Products/Completed Operations Liability)) as one **Claim**, then any later related **Claims** which are made and notified within five (5) years of the Expiration Date of the **Policy Period** are hereby covered under this **Policy** as that one **Claim**, and will be deemed to have been notified at the date of the first designated **Claim** or notification and are subject to one Deductible and one each **Claim** Limit.
- (3) Any **Claims, Damages** or **Claims Expenses** arising from any negligent act, error or omission or **Accident** notified to the Underwriters or other insurer prior to the Inception Date shall not be included as one **Claim** or payable under this **Policy** as **Damages** or **Claims Expenses** arising out of the same, continuing or related negligent act, error or omission or **Accident** of which any **Claim** is made or notice is first given during this **Policy Period**.
- (4) In the absence of any notification and agreement strictly in accordance with the above:
 - (i) the Underwriters shall only be liable for each **Claim** (otherwise properly notified and payable under this **Policy**) on the basis that each remains a separate **Claim**;
 - (ii) no **Claim** made after expiry of the above 120 day period shall be capable of being deemed related to an earlier negligent act, error or omission or **Accident** or **Claim**.

For the purposes of Insuring Agreement I.A.3. (Products/Completed Operations Liability) all **Bodily Injury** or **Property Damage** arising out of one lot of goods, batch, package, or run of products prepared, manufactured or acquired by the **Named Insured** (or by another trading under the **Named Insured's** name) and attributable to a single, direct cause shall be deemed to be one **Claim**.

- E. In the event of non-renewal of this **Insurance** by the Underwriters, the **Insured** shall have sixty (60) days from the Expiration Date of the **Policy Period** to notify the Underwriters of **Claims** made against the **Insured** during the **Policy Period** which arise out of any negligent act, error or omission or **Accident** occurring prior to the termination date of the **Policy Period** and otherwise covered by this **Insurance**.

- F. If any **Insured** shall make any **Claim** under this **Policy** knowing such **Claim** to be false or fraudulent, as regards amount or otherwise, this **Policy** shall become null and void and all coverage hereunder shall be forfeited.

XII. ASSISTANCE AND CO-OPERATION OF THE INSURED

The **Insured** shall co-operate with the Underwriters in all investigations, including regarding the application and coverage under this **Policy**, and upon the Underwriters' request, assist in making settlements, in the conduct of suits and in enforcing any right of contribution or indemnity against any person or organization other than an **Employee** of any **Insured** who may be liable to the **Insured** because of negligent acts, errors or omissions or **Accidents** with respect to which insurance is afforded under this **Policy**. The **Insured** shall attend hearings and trials and assist in securing and giving evidence and obtaining the assistance and attendance of witnesses. The **Insured** shall not, except at its own cost, admit liability, make any payment, assume any obligation, incur any expense, enter into any settlement, stipulate to any judgment or award or otherwise dispose of any **Claim** without the written consent of the Underwriters.

XIII. ACTION AGAINST THE UNDERWRITERS

It is a condition precedent to the Underwriters' liability under this **Policy** that the amount of the **Insured's** obligation to pay shall have been finally determined either by judgment or award against the **Insured** after actual trial or arbitration or by written agreement of the **Insured**, the claimant and the Underwriters. No person or organization shall have any right under this **Insurance** to join the Underwriters as a party to an action or other proceeding against the **Insured** to determine the **Insured's** liability, nor shall the Underwriters be impleaded by the **Insured** or its legal representative.

XIV. BANKRUPTCY

Bankruptcy or insolvency of the **Insured** or of the **Insured's** estate shall not relieve the Underwriters of their obligations hereunder, except that the Underwriters shall not be liable for any sum arising solely as a result of the bankruptcy or insolvency of the **Insured**, and under no circumstances, including such bankruptcy or insolvency, shall the Underwriters be responsible to pay or advance the **Insured's** Deductible, unless the Underwriters choose to do so at their own discretion.

XV. SUBROGATION

If the Underwriters may be liable under this **Insurance**, the Underwriters shall be subrogated to all the **Insured's** rights of recovery against any person or

organization, and the **Insured** shall execute and deliver instruments and papers and do whatever else is necessary to secure such rights. The **Insured** shall do nothing before or after the payment of **Damages** by the Underwriters to prejudice such rights and shall take all reasonable steps to maintain them including positive action where necessary. The obligations of the **Insured** under this Condition XV shall survive this **Policy**.

Any subrogated recovery shall first be paid to the Underwriters to the extent of any **Claims Expenses** paid by them, with the balance then being paid to the Underwriters and the **Insured** in the proportions that they have paid **Damages** in excess of the Deductible, then to the **Insured** for any uninsured loss in excess of the Limit of Liability and then in respect of the Deductible.

Notwithstanding the above the Underwriters may at any time request an assignment from the **Insured** of any cause of action that the **Insured** may have against any third party in respect of which it has been, or appears likely to be, indemnified by the Underwriters, which the **Insured** shall promptly effect.

XVI. CHANGES

Notice to any agent or knowledge possessed by any agent or by any other person shall not effect a waiver or a change in any part of this **Insurance** or estop the Underwriters from asserting any right under the terms of this **Insurance**; nor shall the terms of this **Insurance** be waived or changed, except by endorsement issued to form a part of this **Insurance**, signed by the Underwriters.

XVII. NON-CUMULATION OF LIMITS

Notwithstanding anything to the contrary contained in this **Policy**, if a **Claim** purports to trigger coverage under more than one Insuring Agreement of this **Policy**, the Underwriters' liability under this **Policy** shall not exceed the greater of the Limit of Liability available under any one of the Insuring Agreements provided under this **Policy**.

No **Claim** can trigger coverage or be paid under more than one Insuring Agreement of this **Policy**.

In the event that a **Claim** purports to trigger coverage under more than one policy issued by the Underwriters to the **Named Insured** and its subsidiary companies, any **Claim** or suit will only be covered under the policy with the highest limit of insurance available or, if the limits are the same, under only one of the policies.

XVIII. MERGERS AND ACQUISITIONS

- A. If, during the **Policy Period**, the **Named Insured** is acquired by or acquires an entity (including its subsidiaries) or purchases assets or acquires liabilities and
- (1) the revenues of the acquiring or acquired entity or such assets or liabilities immediately prior to the date of completion of such acquisition do not exceed 10% of the **Named Insured's** annual revenues or assets respectively as specified in its most recent application for insurance to the Underwriters;
 - (2) the business operations of the acquiring or acquired entity are of a similar nature to those of the **Named Insured** as specified in such recent application; and
 - (3) the operations of the acquiring or acquired entity are [primarily] located in the same country as the **Named Insured** or any subsidiary;

then this **Policy** will automatically cover the acquiring or acquired entity from the date of completion of such acquisition but only for **Accidents** or negligent acts, errors or omissions that take place subsequent to completion of such acquisition and for a period from such acquisition of sixty (60) days only. In the event that immediately prior to the date of completion of any such acquisition the total amount of revenues or assets of all acquiring and acquired entities during the **Policy Period** would exceed 25% of the **Named Insured's** annual revenues or assets respectively as specified in such application, Paragraph A. above shall no longer apply and any further acquisitions will be subject to Paragraph B. below.

- B. If during the **Policy Period** the **Named Insured** is acquired by or acquires an entity that does not fall within the criteria detailed in Paragraph A. above, or where Paragraph A. above no longer applies by virtue of the provision contained in its last sentence, this **Policy** shall not apply after the date of completion of such acquisition and the **Named Insured** shall be required to give written notice to the Underwriters prior to the completion of such acquisition by or of the **Named Insured**, and to negotiate with the Underwriters in respect of the additional premium payable and the imposition of any amended terms and conditions in respect of any insurance similar to that provided hereunder that it may require.

XIX. ASSIGNMENT

The interest hereunder of any **Insured** is not assignable except as requested by the Underwriters. If the **Insured** shall die or be adjudged incompetent, such insurance shall cover the **Insured's** legal representative as the **Insured**, as would be permitted by this **Policy**.

XX. CANCELLATION

- A. This **Policy** may be cancelled by the **Named Insured** or by the Underwriters by sending registered or certified mail notice to the other party stating when, not less than sixty (60) days thereafter, cancellation shall be effective.
- B. Any failure of the **Named Insured** to pay the premium or the Deductible when due shall be a repudiatory breach of this **Policy** and the Underwriters shall be entitled to accept such repudiation and cancel this **Policy** on ten (10) days' notice by registered or certified mail to the **Named Insured**. The Underwriters shall be entitled to set off any sum held by them in the discharge of the **Insured's** obligations to the Underwriters or otherwise.
- C. The registration or certification of mailed notice as aforesaid shall be sufficient proof of notice, and this **Insurance** shall end on the effective date and hour of cancellation stated in the notice. Delivery of such written notice either by the **Named Insured** or by the Underwriters shall be equivalent to mailing.
- D. If this **Policy** is cancelled as aforesaid, the Expiration Date of this **Policy** shall be the effective date of such cancellation.
- E. If this **Policy** is cancelled by the **Named Insured**, the Underwriters shall retain the short rate proportion of the premium for the period this **Policy** has been in force, calculated in accordance with the Underwriters' Short Rate Cancellation Table then in force.
- F. If this **Policy** is cancelled by the Underwriters, the Underwriters shall retain the pro rata proportion of the premium for the period this **Policy** has been in force.
- G. Notice of cancellation by the Underwriters shall be effective even though the Underwriters make no payment or tender of return premium with such notice.
- H. The **Named Insured** shall not be entitled to cancel this **Policy** after it has sent notification of a **Claim** or **Circumstance** to the Underwriters.

XXI. ENTIRE CONTRACT

By acceptance of this **Policy**, the **Insured** agrees that the statements in the Declarations and application are his agreements and representations, that this **Insurance** is issued in reliance upon the truth of such representations and that this **Policy** embodies all agreements existing between the **Insured** and the Underwriters relating to this **Insurance**.

XXII. DUTY TO MITIGATE

In the event of any negligent act, error, omission or **Accident** that might give rise to liability under this **Policy**, it is a condition precedent to the underwriters' further liability that the **Insured** shall promptly, at their own expense, take all reasonable steps to prevent or mitigate any other or further or consequential loss, damage or liability arising out of the same or similar conditions, and the Underwriters shall not be liable for any such failure of the **Insured** to do so.

XXIII. INSPECTION AND AUDIT

The Underwriters shall be permitted, but not obligated, to inspect the **Insured's** property, products and operations at any time. Neither the Underwriters' right to make inspections nor the making thereof nor any report thereon shall constitute an undertaking on behalf of or for the benefit of the **Insured** or others, to determine or warrant that such property or operations are safe.

The Underwriters may examine and audit the **Insured's** books and records at any time as far as they relate to the subject matter of this **Insurance**.

XXIV. NAMED INSURED AS AGENT

The **Named Insured** shall be the agent of all **Insureds**, and shall act on behalf of all **Insureds** with respect to the giving of or receipt of all notices pertaining to this **Policy**, the acceptance of any endorsements to this **Policy**, and shall be responsible for the payment of all premiums and Deductibles.

XXV. SEVERAL LIABILITY

The subscribing Underwriters' obligations under contracts of insurance to which they subscribe are several and not joint and are limited solely to the extent of his or her individual subscriptions. The subscribing Underwriters are not responsible for the subscription of any co-subscribing Underwriter who for any reason does not satisfy all or part of its obligations.

XXVI. LICENSURE

- A. It is a condition precedent of the coverage afforded under the **Policy** that the facilities of the **Named Insured** and any **Insured** requiring a license to practice shall be licensed in accordance with all relevant federal, state and local requirements. The **Named Insured** warrants that as of the Inception Date of this **Policy** it has secured all relevant licenses.
- B. If, during the **Policy Period**, any **Insured's** licensure status is altered by withdrawal, revocation, denial, suspension or failure to renew, the **Named Insured** shall give written notice of such change to the Underwriters within thirty (30) days of the change becoming effective. Following receipt of

such notice, the Underwriters may elect, at their sole option, to revise any Insuring Agreements, Definitions, Limitations, Exclusions, Endorsements or other Conditions of this **Policy** with respect to the **Insured**, with effect from such date of such withdrawal, revocation, denial, suspension or failure to renew. Such action does not waive the Underwriters' option to invoke the provisions of Section XX of this **Policy**. Furthermore, the Underwriters will have no obligation to respond to any **Claim** arising out of **Clinical Research Services** or **Healthcare Professional Services** which took place subsequent to the date of the withdrawal, revocation, denial, suspension or failure to renew.

XXVII. NUCLEAR INCIDENT EXCLUSION

The insurance provided by this **Policy** does not apply:

- A. To injury sickness, disease, death or destruction
 - (1) with respect to which an **Insured** under this **Policy** of insurance is also an **Insured** under a nuclear energy liability insurance issued by Nuclear Energy Liability Insurance Association, Mutual Atomic Energy Liability Underwriters or Nuclear Insurance Association of Canada or would be an **Insured** under any such insurance but for its termination upon exhaustion of its limits of liability; or
 - (2) resulting from the hazardous properties of nuclear material and with respect to which (i) any person or organization is required to maintain financial protection pursuant to the Atomic Energy Act of 1954, or any law amendatory thereof, or (ii) the **Insured** is, or had this insurance not been issued would be, entitled to indemnity from the United States of America, or any agency thereof under any agreement entered into by the United States of America, or any agency thereof, with any person or organization.
- B. Under any Medical Payments Coverage, or under any Supplementary Payments Provision relating to immediate medical or surgical relief, to expenses incurred with respect to bodily injury, sickness, disease or death resulting from the hazardous properties of nuclear material and arising out of the operation of a nuclear facility by any person or organization.
- C. To injury, sickness, disease, death or destruction resulting from the hazardous properties of nuclear material, if:
 - (1) the nuclear material (i) is at any nuclear facility owned by, or operated by or on behalf of, an **Insured** or (ii) has been discharged or dispersed there from;

- (2) the nuclear material is contained in spent fuel or waste at any time possessed, handled, used, processed, stored, transported or disposed of by or on behalf of an **Insured**; or
- (3) the injury, sickness, disease, death or destruction arises out of the furnishing by an **Insured** of services, materials, parts or equipment in connection with the planning, construction, maintenance, operation or use of any nuclear facility, but if such facility is located within the United States of America, its territories or possessions or Canada, this exclusion (3) applies only to injury to or destruction of property at such nuclear facility.

D. As used in this clause: "hazardous properties" include radioactive, toxic or explosive properties; "nuclear material" means source material, special nuclear material or by-product material; "source material", "special nuclear material" and "by-product material" have the meanings given them in the Atomic Energy Act of 1954 or in any law amendatory thereof, "spent fuel" means any fuel element or fuel component, solid or liquid, which has been used or exposed to radiation in a nuclear reactor; "waste" means any waste material (i) containing by-product material and (ii) resulting from the operation by any person or organization of any nuclear facility under paragraph (1) or (2) thereof; "nuclear facility" means

- (1) any nuclear reactor;
- (2) any equipment or device designed or used for (i) separating the isotopes of uranium or plutonium, (ii) processing or utilizing spent fuel, or (iii) handling, processing or packaging waste;
- (3) any equipment or device used for the processing, fabricating or alloying of special nuclear material if any time the total amount of such material in the custody of the **Insured** at the premises where such equipment or device is located consists of or contains more than 25 grams of plutonium or uranium 233 or any combination thereof, or more than 250 grams of uranium 235; or
- (4) any structure, basin, excavation, premises or place prepared or used for the storage or disposal of waste;

and includes the site on which any of the foregoing is located, all operations conducted on such site and all premises used for such operations; "nuclear reactor" means any apparatus designed or used to sustain nuclear fission in self-supporting chain reaction or to contain a critical mass of fissionable material. With respect to injury to or destruction of property, the word "injury" or "destruction" includes all forms of radioactive contamination of property.

Except as specifically provided herein, this clause XXVII is subject to the terms, exclusions, conditions and limitations of this **Insurance**.

However, this exclusion will not apply to a **Patient** in receipt of **Clinical Research Services** or **Healthcare Professional Services**.

XXVIII. SERVICE OF SUIT

- A. In the event of the failure of the Underwriters hereon to pay any amount claimed to be due under this **Insurance**, the Underwriters hereon, at the request of the **Named Insured**, will submit to the jurisdiction of a court of competent jurisdiction within the United States. This Condition does not constitute and should not be understood to constitute an agreement by the Underwriters that an action is properly maintained in a specific forum, nor may it be construed as a waiver of the Underwriters' rights to commence an action in a court of competent jurisdiction in the United States, to remove an action to a United States District Court, or to seek a transfer of a case to another court as permitted by the laws of the United States or of any state of the United States, all of which rights the Underwriters expressly reserve. It is further agreed that service of process in such suit may be made upon the designated entity in Item 7 of the Declarations, and that in any suit instituted against any one of them upon this contract, the Underwriters will abide by the final decision of such court in the event of an appeal.
- B. The entity designated in Item 7 of the Declarations is authorized and directed to accept service of process on behalf of the Underwriters in any such suit and/or upon the request of the **Named Insured** to give written undertaking to the **Named Insured** that they will enter a general appearance upon the Underwriters' behalf in the event such a suit shall be instituted. Further, pursuant to any statute of any state, territory or district of the United States which makes provision therefore, the Underwriters hereon hereby designate the Superintendent, Commissioner or Director of Insurance or other officer specified for that purpose in the statute or his successor or successors in office, as their true and lawful attorney upon whom may be served any lawful process in any action, suit or proceedings instituted by or on behalf of the **Named Insured** or any beneficiary hereunder arising out of this contract of insurance, and hereby designates the entity, designated in Item 7 of the Declarations, as the person to whom the said officer is authorized to mail such process or a true copy thereof.

XXIX. CHOICE OF LAW

Any disputes involving any aspect of this **Policy** shall be resolved applying the law designated in Item 11. of the Declarations.