

LIFE SCIENCE SPECIALTY LIABILITY POLICY (DEFENSE INSIDE THE LIMITS)

THIS IS A CLAIMS MADE POLICY. THE COVERAGE AFFORDED BY THIS POLICY IS LIMITED TO "CLAIMS" FIRST MADE AGAINST THE "INSURED" DURING THE POLICY TERM OR ANY APPLICABLE EXTENDED REPORTING PERIOD IN ACCORDANCE WITH THE COMMON CONDITIONS AND DUTIES IN THE EVENT OF A "CLAIM." "DEFENSE COSTS" COVERED BY THIS POLICY ARE SUBJECT TO, WILL REDUCE AND MAY EXHAUST THE LIMITS OF INSURANCE.

WE HAVE NO DUTY TO PROVIDE COVERAGE UNDER THIS POLICY UNLESS THERE HAS BEEN FULL COMPLIANCE WITH ALL OF THE CONDITIONS OF THIS POLICY.

WE HAVE ISSUED THIS POLICY RELYING UPON THE REPRESENTATIONS MADE AND INFORMATION CONTAINED IN THE "APPLICATION" FOR THIS INSURANCE, INCLUDING ALL ASSOCIATED SUBMITTED DOCUMENTS. THE "APPLICATION" IS HEREBY INCORPORATED AS A PART OF THIS POLICY.

VARIOUS PROVISIONS IN THIS POLICY RESTRICT COVERAGE. PLEASE READ THIS POLICY CAREFULLY IN ITS ENTIRETY TO DETERMINE RIGHTS, DUTIES AND WHAT IS AND IS NOT COVERED.

Throughout this policy the words we, our and us refer to the company providing this insurance. Other key words and phrases that appear in "quotations" have special meanings. Refer to **SECTION IX—DEFINITIONS**.

SECTION I—PRODUCTS-WORK HAZARD LIABILITY COVERAGE

A. INSURING AGREEMENT

We will pay those sums that the "insured" becomes legally obligated to pay as "damages" and "defense costs" for:

1. "Bodily injury" or "property damage," included in the "products-work hazard"; or
2. "Personal and advertising injury," but solely to the extent such "personal and advertising injury" arises out of a "clinical trial" to which this insurance applies.

We will have the right and duty to defend the "insured" against any "claim" or "suit" seeking those "damages."

However, we will have no duty to defend the "insured" against any "suit" seeking "damages" to which this insurance does not apply. We may, at our discretion, investigate any "occurrence" or offense and settle any "claim" or "suit" that may result. But:

1. The amount we pay for "damages" and "defense costs" is limited as described in **SECTION V—LIMITS OF INSURANCE**; and
2. Our right and duty to defend ends when we have exhausted the applicable Limit of Insurance.

No other obligation or liability to pay sums or perform acts or services is covered unless explicitly provided for under **SECTION III—SUPPLEMENTAL COVERAGES**.

This insurance applies only if:

1. The “bodily injury,” “property damage” or “personal and advertising injury”:
 - a. Is caused by an “occurrence” or offense that takes place in the “coverage territory”; and
 - b. First occurred:
 - (1) On or after the Retroactive Dates, if any, shown in the Declarations; and
 - (2) Before the end of the policy term; and
2. A “claim” or “suit” for “damages” for the “bodily injury,” “property damage” or “personal and advertising injury” is first made against an “insured”:
 - a. During the policy term; or
 - b. During any Extended Reporting Periods, in accordance with the provisions of **SECTION VIII—COMMON CONDITIONS**, subsection T. **EXTENDED REPORTING PERIODS**; and
 - c. In accordance with the provisions of the **SECTION VIII—COMMON CONDITIONS** of this policy; and
3. Prior to the effective date of the policy term:
 - a. No “executive officer” knew of or had a basis to believe:
 - (1) That any “bodily injury” or “property damage” had occurred; or
 - (2) That any offense giving rise to “personal and advertising injury” had occurred;
 - b. No “insured” gave notice to a prior insurer of any such “circumstance” or associated “claim” or “suit”; and
 - c. Neither an “insured” nor any prior insurer made a written declaration of a “related claim”; and
4. All applicable provisions of **SECTION VII—DEEMED MADE** are met.

B. PRODUCTS-WORK HAZARD EXCLUSIONS

In addition to any exclusions listed in **SECTION IV—COMMON POLICY EXCLUSIONS**, this insurance does not apply to:

1. Auto Liability

Any “bodily injury” or “property damage” arising out of the ownership, maintenance, operation, use, loading or unloading or entrustment to others of any “auto.”

2. Contractual Liability

“Bodily injury,” “property damage” or “personal and advertising injury” for which any “insured” is obligated to pay “damages” by reason of the assumption of liability in a contract or agreement.

This exclusion does not apply to liability for “damages”:

- a. For which any “insured” would have been liable in the absence of the contract or agreement; or
- b. Assumed in a contract or agreement that is an “insured contract.”

Solely for the purposes of liability assumed in an “insured contract,” reasonable attorney fees and necessary litigation expenses incurred by or for a party other than an “insured” because of “bodily injury,” “property damage” or “personal and advertising injury,” are deemed to be part of “defense costs” provided:

- (1) Liability to such party for, or for the cost of, that party's defense has also been assumed in the same "insured contract"; and
- (2) Such attorney fees and litigation expenses are for defense of that party against a civil or alternative dispute resolution proceeding that alleges "damages" to which this insurance applies.

3. **Illegal Materials and Unapproved Goods or Unapproved Products**

"Bodily injury," "property damage" or "personal and advertising injury" based on or arising out of:

- a. Knowingly violating any law, order, ordinance, regulation or statute by any "insured" or any entity operating on behalf of any "insured";
- b. The actual, alleged or threatened hazardous properties of any goods or products declared to be unsafe by the applicable governmental or regulatory authority having jurisdiction on the basis of such hazardous properties, regardless of whether or not such goods or products were declared unsafe before or after:
 - (1) The goods or products were disposed of, distributed, handled, manufactured or sold;
 - (2) Such "damages," cost or expenses were incurred; or
 - (3) The goods or products were disposed of, distributed, handled, manufactured or sold without approval of the applicable governmental or regulatory authority having jurisdiction.

Subparagraph **b.(1)** above does not apply to "insured product," if such good or product was disposed of, distributed, handled, manufactured or sold before it was known by the "insured" or would have been known from the standpoint of a reasonable person in the "insured's" position, that the good or product had been declared unsafe.

For purposes of determining the applicability of this exclusion:

- (1) The facts pertaining to and knowledge possessed by any "insured" shall not be imputed to any other natural person "insured"; and
- (2) Only facts pertaining to and knowledge possessed by any "insured" as set forth under paragraph 1. of the definition of "insured" in the **SECTION IX—DEFINITIONS** shall be imputed to the "insured."

4. **Recording and Distribution of Material or Information in Violation of Law**

"Bodily injury," "property damage" or "personal and advertising injury" arising out of any actual or alleged violation of:

- a. The Telephone Consumer Protection Act (TCPA), including any amendment of or addition to such law;
- b. The CAN-SPAM Act of 2003, including any amendment of or addition to such law;
- c. The Fair Credit Reporting Act (FCRA), and any amendment of or addition to such law, including the Fair and Accurate Credit Transaction Act (FACTA);
- d. Any applicable law, order, ordinance, regulation or statute other than the TCPA, CAN-SPAM Act of 2003, or FCRA, including FACTA, and their amendments and additions, that addresses, prohibits, or limits the printing, dissemination, disposal, collecting, recording, sending, transmitting, communicating or distribution of information or material;
- e. Any unauthorized or unsolicited electronic communication to advertise or promote a good, product, service or Internet website; or

- f. Any applicable law, order, ordinance, regulation or statute which prohibits or limits the conversion or consumption of another's tangible property or electronic assets including minute allowances, text message allowances, and other electronic consumables.

5. Employer's Liability

"Bodily injury" to:

- a. An "employee" of the "Insured Entity" arising out of and in the course of:
 - (1) Employment by the "Insured Entity"; or
 - (2) Performing duties related to the conduct of the "Insured Entity's" business; or
- b. The spouse, "domestic partner," child, parent, brother or sister of that "employee" as a consequence of subparagraph a. above.

This exclusion applies whether the "Insured Entity" may be liable as an employer or in any other capacity; and to any obligation to share "damages" with or repay someone else who must pay "damages" because of the injury.

Voluntary participation as a human test subject in a "clinical trial" will not be deemed to be within the course of employment or performance of duties as described in subparagraphs a. and b. above.

6. Environmental Laws, Failure to Comply

"Bodily injury," "property damage" or "personal and advertising injury" arising out of any failure to comply with any environmental law, order, ordinance, regulation or statute, if such failure is a deliberate or willful act or omission by or on behalf of any "insured."

7. Expected or Intended Injury

"Bodily injury," "property damage" or "personal and advertising injury" expected or intended from the standpoint of any "insured." This exclusion does not apply to:

- a. "Bodily injury" or "property damage" arising out of any use of reasonable force to protect persons or property;
- b. "Bodily injury" that is intended or can be expected to result from reasonable use of "insured product"; or
- c. The liability for "damages" and "defense costs" for "bodily injury" that results from:
 - (1) Reasonable use of a "life science product" within or upon test subjects during a "clinical trial" to which this insurance applies; or
 - (2) A procedure or service to remove, repair or replace "insured product" which has been put inside a person's body, if:
 - i. Such product is a "medical device" that has caused "bodily injury" to such person before such procedure or service; and
 - ii. Such removal, repair or replacement is necessary to prevent a change, continuation or resumption of such "bodily injury" to such person.

8. Governmental Claims or Proceedings

"Bodily injury," "property damage" or "personal and advertising injury" based on, arising out of or in any way related to any "claim" or "suit," proceeding, investigation, order or regulation made by or on behalf of any governmental entity unless such "claim" or "suit" is brought by a government entity solely in its capacity as client of an "insured" and which arises out of an "insured contract."

9. Life Science Professional Liability

Any “damages” or “defense costs” for “professional services injury” covered under **SECTION II—LIFE SCIENCE PROFESSIONAL LIABILITY COVERAGE.**

10. Contractual Breach

“Personal and advertising injury” based on or arising out of any actual or alleged breach of contract, except an implied contract to use another’s advertising idea in the “Insured Entity’s” “advertisement.”

11. Electronic Bulletin Boards, Blog or Chat Rooms

“Personal and advertising injury” based on or arising out of any actual or alleged posting, publication or hosting of material in or on electronic chat rooms, blogs or bulletin boards the “insured” hosts, owns, or over which the “insured” exercises control.

12. Material Published with Knowledge of Falsity

“Personal and advertising injury” based on or arising out of any actual or alleged oral or written publication of material or information in any form, if the “insured” knew or should have known the material or information in any form was false.

13. Quality or Performance of Goods—Failure to Conform to Statements

“Personal and advertising injury” based on or arising out of any actual or alleged failure of goods, products or services to conform to any statement of performance, quality or warranty made in the “Insured Entity’s” “advertisement.”

14. Wrong Description of Prices

“Personal and advertising injury” based on or arising out of any actual or alleged wrong description of the price of goods, products or services stated in the “Insured Entity’s” “advertisement.”

15. Property Damage to Impaired Property

“Property damage” to “impaired property” or property that has not been physically injured, arising out of:

- a. A defect, deficiency, inadequacy or dangerous condition in “insured product” or “insured work”; or
- b. A delay or failure by the “Insured Entity” or someone acting on its behalf to perform a contract or agreement in accordance with its terms.

The exclusion does not apply to the loss of use of other property arising out of sudden and accidental physical injury to “insured product” or “insured work” after it has been put to its intended use.

16. Damage to Property

“Property damage” to:

- a. Property the “Insured Entity” or anyone operating on the “Insured Entity’s” behalf owns, rents, or occupies, including any costs or expenses incurred by the “Insured Entity,” or any other person, 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;
- b. Premises the “Insured Entity” sells, gives away or abandons, if the “property damage” arises out of any part of those premises;

- c. Property loaned to the “Insured Entity”; or
- d. Personal property in the care, custody or control of any “insured.”

This exclusion does not apply to **CARE, CUSTODY OR CONTROL PROPERTY DAMAGE EXPENSE REIMBURSEMENT** provided under **SECTION III—SUPPLEMENTAL COVERAGES**.

17. Damage to Insured Product

“Property damage” to “insured product” arising out of it or any part of it and included in the “products-work hazard.”

18. Damage to Insured Work

“Property damage” to “insured work” arising out of it or any part of it and included in the “products-work hazard.”

This exclusion does not apply if the damaged work or the work out of which the damage arises was performed on the “Insured Entity’s” behalf by a subcontractor.

19. Recall of Insured Product

“Claims” or “suits” for any loss, cost or expense incurred for the adjustment, disposal, inspection, loss of use, recall, repair, replacement, removal or withdrawal of:

- a. “Insured product”;
- b. “Insured work”; or
- c. “Impaired property”;

if such product, work, or property is withdrawn or recalled from the market or from use by any person or organization because of a known or suspected defect, deficiency, inadequacy or dangerous condition.

This exclusion does not apply to:

(1) “Bodily injury” including “bodily injury” that results from a procedure or service to remove “insured product” from or repair or replace “insured product” that has been placed inside a person’s body if:

- i. Such product is a “medical device” that has caused “bodily injury” to such person before such procedure or service; and
- ii. Such removal, repair or replacement is necessary to prevent a change, continuation or resumption of such “bodily injury” to such person; or

(2) **CLASS 1 PRODUCT RECALL EXPENSES REIMBURSEMENT** provided under **SECTION III—SUPPLEMENTAL COVERAGES**.

We will not pay for the cost of the “insured product” or its replacement under the exception for “bodily injury” described in this exclusion.

20. Unapproved Clinical Trials

“Bodily injury,” “property damage” or “personal and advertising injury” arising out of any unapproved exposure to material in connection with any “clinical trial” that happens after:

- a. A hold has been placed on the “clinical trial”;
- b. An investigational New Drug Application, Investigational Device Exception Application or similar authorization applicable to the “clinical trial” has been withdrawn; or

c. The “clinical trial” has been ordered to be discontinued;
by the applicable governmental or regulatory authority having jurisdiction.

21. Unapproved Off-Label Promotion

“Bodily injury,” “property damage” or “personal and advertising injury” arising out of any dissemination of information:

- a. By or on behalf of any “insured”; and
- b. In connection with any unapproved use of any “life science product”;

in violation of any law, order, ordinance, regulation or statute of any governmental or regulatory authority.

This exclusion does not apply if the “insured” did not intend or a reasonable person in the “insured’s” position would not have expected that such information would be used to encourage or promote any such unapproved use.

22. Workers’ Compensation and Similar Laws

Any obligation of the “insured” under a workers’ compensation, disability benefits or unemployment compensation law or any similar law.

23. Electronic Data

“Damages” or “defense costs” arising out of the loss of, loss of use of, damage to, corruption of, inability to access, or inability to manipulate electronic data.

However, this exclusion does not apply to liability for “damages” and “defense costs” because of “bodily injury” resulting from “insured product” or “insured work” to which this insurance applies.

As used in this exclusion, electronic data means facts, concepts and information converted to a form useable for communications, interpretation or processing by electronic and electromechanical data processing or electronically controlled equipment and includes programs, software and other coded instructions for the processing and manipulation of data or the direction and manipulation of such equipment.

SECTION II—LIFE SCIENCE PROFESSIONAL LIABILITY COVERAGE

A. INSURING AGREEMENT

We will pay those sums that the “insured” becomes legally obligated to pay as “damages” and “defense costs” for “professional services injury” to which this insurance applies.

We will have the right and duty to defend the “insured” against any “claim” or “suit” seeking those “damages.”

However, we will have no duty to defend the “insured” against any “suit” seeking “damages” to which this insurance does not apply. We may, at our discretion, investigate any “wrongful act” and settle any “claim” or “suit” that may result. But:

1. The amount we will pay for “damages” and “defense costs” is limited as described in **SECTION V—LIMITS OF INSURANCE**; and
2. Our right and duty to defend ends when we have used up the applicable Limit of Insurance.

No other obligation or liability to pay sums or perform acts or services is covered unless explicitly provided for under **SECTION III—SUPPLEMENTAL COVERAGES**.

This insurance applies only if the “professional services injury”:

1. Is caused by or results from a “wrongful act” that takes place in the “coverage territory”;
2. Arises out of “professional services”;
3. First occurred:
 - a. On or after the Retroactive Dates, if any, shown in the Declarations; and
 - b. Before the end of the policy term;
4. Results in a “claim” for “damages” and “defense costs” that is first made against an “insured”:
 - a. During the policy term; or
 - b. During any Extended Reporting Periods, in accordance with the provisions of **SECTION VIII—COMMON CONDITIONS**, subsection **T. EXTENDED REPORTING PERIODS**; and
 - c. Made in accordance with the provisions of the **SECTION VIII—COMMON CONDITIONS**;
5. Prior to the effective date of the policy term:
 - a. No “executive officer” knew or had a basis to believe that any “professional services injury” had occurred;
 - b. No “insured” gave notice to a prior insurer of any circumstance or associated “claim” or “suit”; and
 - c. Neither an “insured” nor any prior insurer made a written declaration of a “related claim”; and
6. All applicable provisions of **SECTION VII—DEEMED MADE** are met.

B. LIFE SCIENCE PROFESSIONAL LIABILITY EXCLUSIONS

In addition to any exclusions listed in **SECTION IV—COMMON POLICY EXCLUSIONS**, this insurance does not apply to:

1. Conversion of Funds

Any “professional services injury” based on or arising out of any actual or alleged conversion, commingling, defalcation, misappropriation or improper use of funds or other property; or, the gaining of any personal profit or advantage to which an “insured” is not legally entitled.

2. Discrimination, Harassment, Humiliation

Any “professional services injury” based on or arising out of any actual or alleged discrimination, harassment or humiliation, that includes, but shall not be limited to “professional services injury” based on or arising out of an individual’s race, creed, color, age, gender, national origin, religion, disability, marital status or sexual orientation or an organization’s political or religious affiliations or any other status under any applicable law, order, ordinance, regulation or statute.

3. Directors’ and Officers’ or Fiduciary Liability

Any “professional services injury” based on or arising out of an “insured’s” capacity as:

- a. A former, existing or prospective officer, director, shareholder, partner or manager of a business enterprise or charitable organization (if the above are not named in the Declarations);
- b. A former, existing or prospective officer, director, shareholder, partner manager, or trustee of a fund or trust that is a pension, welfare, profit-sharing, mutual or investment fund or trust; or

- c. A fiduciary under the Employee Retirement Income Security Act of 1974 and its amendments or any regulation or order issued pursuant thereto or any other similar law, order, ordinance, regulation or statute.

4. Life Science Products-Work Hazard

Any “damages” or “defense costs” for “bodily injury,” “property damage” or “personal and advertising injury” covered under **SECTION I—PRODUCTS-WORK HAZARD LIABILITY COVERAGE**.

5. Misuse of Confidential Information

Any “professional services injury” based on or arising out of any actual or alleged use or misuse of confidential or proprietary information.

6. Other Specialized Professional Services

Any “professional services injury” based on or arising out of the performance of or failure to perform any of the following services:

- a. Accounting;
- b. Insurance;
- c. Actuarial;
- d. Legal;
- e. Architectural;
- f. Engineering; or
- g. Surveying.

This exclusion applies regardless of whether a “professional services injury” is alleged by any client of an “insured” or by any other person or organization, and regardless of whether any such “professional services” are ordinary to any “insured’s” profession.

SECTION III—SUPPLEMENTAL COVERAGES

A. CARE, CUSTODY OR CONTROL PROPERTY DAMAGE EXPENSE REIMBURSEMENT

1. We will reimburse the “Insured Entity” for “care, custody or control property damage expenses” provided that:
 - a. The obligation for “care, custody or control property damage expenses” is assumed under an “insured contract”;
 - b. The “Insured Entity” reports the “circumstance,” or “claim” for which the “Insured Entity” intends to incur such “care, custody or control property damage expenses” in accordance with **SECTION VIII—COMMON CONDITIONS**; and
 - c. We provide written approval of any “care, custody or control property damage expenses” prior to such expenses being incurred.
2. This coverage only applies if:
 - a. The “property damage” is caused by an “occurrence” that takes place in the “coverage territory” and first occurred:
 - (1) On or after the Retroactive Dates shown in the Declarations; and
 - (2) Before the end of the policy term;

- b. The “care, custody or control property damage expenses” are reported to us during the policy term or if applicable, the Extended Reporting Period, in accordance with the provisions of **SECTION VIII—COMMON CONDITIONS**, subsection **T. EXTENDED REPORTING PERIODS**; and
 - c. Prior to the policy term no “executive officer” had prior knowledge of any potential need for such “care, custody or control property damage expenses.”
3. We will not pay for any “care, custody or control property damage expenses” for “property damage” covered under any bailees or warehouse coverage.
 4. We will make these payments regardless of fault; however, we will not pay expenses for “property damage” otherwise excluded under this policy. Payment of “care, custody or control property damage expenses” is not an acknowledgement by us that a “claim” or “suit” is a covered loss under this insurance.
 5. The Each Occurrence Care, Custody or Control Property Damage Expense Reimbursement Limit shown in the Declarations is the most we will pay for each “occurrence.” The Care, Custody or Control Property Damage Expense Reimbursement Aggregate Limit shown in the Declarations is the most we will pay for all “care, custody or control property damage expenses” during the policy term. These limits are part of, will reduce and are not in addition to, the Policy Aggregate Limit of Insurance shown in the Declarations.

This Supplemental Coverage is excess over any valid and collectable insurance available to the “Insured Entity” to cover such “property damage,” regardless of whether the other insurance is written under the same terms and conditions.

B. DATA BREACH COVERAGE

Data Breach Liability Coverage

We will pay those sums the “insured” becomes legally obligated to pay as “damages” and “defense costs” for “data breach economic injury” arising out of “insured product,” “insured work” or “professional services” performed by the “Insured Entity” or on its behalf if such “data breach economic injury” is caused by or arises out of an “insured’s” “data breach.”

1. We will not pay for:
 - a. Any “data breach economic injury” if the “insured” had knowledge that the “data breach” would violate the rights of another and inflict “data breach economic injury”; or
 - b. “Data breach expenses.”
2. This coverage only applies if:
 - a. The “data breach” first occurs:
 - (1) On or after the Retroactive Dates, if any, shown in the Declarations; and
 - (2) Before the end of the policy term;
 - b. A “claim” or “suit” for such “data breach economic injury” is first made against an “insured” during the policy term, or if applicable, the Extended Reporting Period, in accordance with the provisions of **SECTION VIII—COMMON CONDITIONS**, subsection **T. EXTENDED REPORTING PERIODS**; and
 - c. Prior to the effective date of the policy term:
 - (1) No “executive officer” knew or had a basis to believe that any “data breach” had occurred;
 - (2) No “insured” gave notice to a prior insurer of any “circumstance” or associated “data breach”; and

- (3) Neither an “insured” nor any prior insurer made a written declaration of a “related claim”;
 - d. All applicable provisions of **SECTION VII—DEEMED MADE** are met; and
 - e. The “insured” gives written notice to us as soon as practicable after the discovery of a “data breach,” but in no event later than thirty (30) days after the “insured” first discovers such “data breach” or a reasonably suspected “data breach.”
3. The Each Data Breach Liability Limit shown in the Declarations is most we will pay for each reported “data breach.” The Data Breach Liability Aggregate Limit shown in the Declarations is the most we will pay for all “data breaches” during the policy term. These limits are part of, and not in addition to, the Policy Aggregate Limit of Insurance shown in the Declarations.

Data Breach Expense Reimbursement

1. We will reimburse the “Insured Entity” for “data breach expenses” incurred due to a “data breach,” to which this insurance applies provided that:
- a. The “Insured Entity” reports the “data breach” for which the “Insured Entity” intends to incur such “data breach expenses” as soon as practicable after the discovery of a “data breach,” but in no event later than thirty (30) days after the “insured” first discovers such “data breach” or a reasonably suspected “data breach”;
 - b. The “Insured Entity” provides us with details of the action being contemplated by the “Insured Entity” to minimize any potential “damages” or “defense costs” arising out of such “data breach” and the amount of “data breach expenses” that are contemplated in connection with such action; and
 - c. We provide written approval of any “data breach expenses” prior to such expenses being incurred.
2. This coverage only applies if:
- a. The “data breach expenses” are reported to us during the policy term or if applicable, the Extended Reporting Period in accordance with the provisions of **SECTION VIII—COMMON CONDITIONS**, subsection **T. EXTENDED REPORTING PERIODS**; and
 - b. Prior to the policy term no “executive officer” had prior knowledge of any potential “data breach” for which the “Insured Entity” intends to incur such “data breach expenses.”
3. We will make these payments regardless of fault; however, we will not pay expenses for a “data breach” otherwise excluded under this policy. Payment of “data breach expenses” is not an acknowledgment by us that “damages” or “defense costs” for “data breach economic injury” are covered under this insurance.
4. The Each Data Breach Expense Reimbursement Limit shown in the Declarations is the most we will pay for each “data breach.” The Data Breach Expense Reimbursement Aggregate Limit shown in the Declarations is the most we will pay for all “data breach expenses” during the policy term. These limits are part of, will erode and are not in addition to, the Policy Aggregate Limit of Insurance shown in the Declarations.

This Supplemental Coverage is excess over any valid and collectable insurance available to you to cover such “data breach,” regardless of whether the other insurance is written under the same terms and conditions.

C. MEDICAL EXPENSE REIMBURSEMENT

1. We will reimburse the “Insured Entity” for “medical expenses” for “bodily injury” caused by an “occurrence” that happens in connection with the conduct of a “clinical trial,” provided that:

- a. The “medical expenses” are incurred by the “Insured Entity” and reported to us within one year of the date of the “occurrence”;
 - b. The injured person submits to examination, at our expense, by healthcare professionals of our choice as often as we reasonably require; and
2. This coverage only applies if:
- a. The “occurrence” takes place in the “coverage territory” and first occurred:
 - (1) On or after the Retroactive Dates shown in the Declarations; and
 - (2) Before the end of the policy term;
 - b. A “claim” for such “medical expense” is first made against an “insured” during the policy term, or if applicable, the Extended Reporting Period, in accordance with the provisions of **SECTION VIII—COMMON CONDITIONS**, subsection **T. EXTENDED REPORTING PERIODS**; and
 - c. Prior to the policy term no “executive officer” had prior knowledge of any potential need for such “medical expenses.”
3. We will make these payments regardless of fault, however, we will not pay expenses for “bodily injury” otherwise excluded under this policy. Payment of “medical expenses” is not an acknowledgment by us that “damages” or “defense costs” for “bodily injury” are covered under this insurance.
4. The Each Person Medical Expense Reimbursement Limit shown in the Declarations is most we will pay for each injured person. The Medical Expense Reimbursement Aggregate Limit shown in the Declarations is the most we will pay for all “medical expense” during the policy term. These limits are separate from, and will not reduce, the Policy Aggregate Limit of Insurance shown in the Declarations.

D. CRISIS MITIGATION EXPENSE REIMBURSEMENT

1. We will reimburse the “Insured Entity” for “crisis mitigation expenses” provided that:
- a. The “Insured Entity” reports the “circumstance,” “claim” or “suit” for which the “Insured Entity” intends to incur such “crisis mitigation expenses” in accordance with the **SECTION VIII—COMMON CONDITIONS**;
 - b. The “Insured Entity” provides us with details of the action being contemplated by the “Insured Entity” to minimize any potential “damages” and “defense costs” arising out of such “circumstance,” “claim” or “suit” and the amount of “crisis mitigation expenses” that are contemplated in connection with such action;
 - c. We provide written approval of any “crisis mitigation expenses” prior to such expenses being incurred; and
 - d. The “Insured Entity” cooperates with us in addressing the “circumstance,” “claim” or “suit” for which the “crisis mitigation expenses” are being incurred.
2. This coverage only applies if:
- a. The “circumstance” for which the “Insured Entity” intends to incur such “crisis mitigation expenses” takes place in the “coverage territory” and first occurred:
 - (1) On or after the Retroactive Dates shown in the Declarations; and
 - (2) Before the end of the policy term; and
 - b. The “crisis mitigation expenses” are reported to us during the policy term or if applicable, the Extended Reporting Period, in accordance with the provisions of **SECTION VIII—COMMON CONDITIONS**, subsection **T. EXTENDED REPORTING PERIODS**; and

- c. Prior to the policy term no “executive officer” had prior knowledge of any potential “circumstance,” “claim” or “suit” for which the “Insured Entity” intends to incur such “crisis mitigation expenses.”
3. We will make these payments regardless of fault; however, we will not pay expenses for any “circumstance,” “claim” or “suit” otherwise excluded under this policy. Payment of “crisis mitigation expenses” is not an acknowledgment by us that a “circumstance,” “claim” or “suit” is a covered loss under this insurance.
4. The Each Circumstance Crisis Mitigation Expense Reimbursement Limit shown in the Declarations is most we will pay for each reported “circumstance,” “claim” or “suit.” The Crisis Mitigation Expense Reimbursement Aggregate Limit shown in the Declarations is the most we will pay for all “crisis mitigation expenses” during the policy term. These limits are part of, not in addition to, the Policy Aggregate Limit of Insurance shown in the Declarations.

This Supplemental Coverage is excess over any valid and collectable insurance available to you to cover such “crisis mitigation expenses” regardless of whether the other insurance is written under the same terms and conditions.

E. CLASS 1 PRODUCT RECALL EXPENSES REIMBURSEMENT

1. We will reimburse the “Insured Entity” for “class 1 product recall expenses” provided that:
 - a. The “Insured Entity” reports the “class 1 product recall” for which the “Insured Entity” intends to incur such “class 1 product recall expenses” as soon as practicable after the knowledge of a “class 1 product recall,” but in no event later than thirty (30) days after the “insured” first has knowledge of a “class 1 product recall.”
 - b. The “Insured Entity” provides us with details of the action being contemplated to minimize any potential “damages” and “defense costs” arising out of such “class 1 product recall” and the amount of “class 1 product recall expenses” that are contemplated in connection with such action;
 - c. We provide written approval of any “class 1 product recall expenses” prior to such expenses being incurred; and
 - d. The “Insured Entity” cooperates with us in addressing the “class 1 product recall” for which the “class 1 product recall expenses” are being incurred.
2. This coverage only applies if:
 - a. The “class 1 product recall” is initiated during the policy term;
 - b. The “class 1 product recall expenses” are reported to us during the policy term or if applicable, the Extended Reporting Period, in accordance with the provisions of **SECTION VIII—COMMON CONDITIONS**, subsection **T. EXTENDED REPORTING PERIODS**; and
 - c. Prior to the policy term no “executive officer” had prior knowledge of any potential need for such “class 1 product recall.”
3. We will not pay for:
 - a. “Class 1 product recall expenses” that result from a procedure or service to:
 - (1) Remove “insured product” from;
 - (2) Repair or replace “insured product” which has been placed inside a person or animal; or
 - (3) The cost of “insured product,” explanation of said product or its replacement.

- b. "Class 1 product recall expenses" due to expenses incurred based on:
- (1) Caprice or whim of any "insured";
 - (2) Deterioration, decomposition or transformation of a chemical nature, except if caused by an error in the design, compounding, distributing, handling, labeling, manufacturing, production, processing, propagation, packaging, storage or transportation of "insured product";
 - (3) Improper, inadequate or faulty compound, formula or specifications, unless there is a reasonable probability that such improper, inadequate or faulty compound, formula or specifications will cause "bodily injury" or "property damage";
 - (4) Failure of "insured product" to accomplish its intended purpose, whether written or implied, including any breach of warranty of fitness, quality, efficacy or efficiency;
 - (5) Any knowledge, fact or situation that at the inception of the policy term or the date the "Insured Entity" relinquished "insured product" to others;
 - (a) Was known to any "insured"; or
 - (b) Was reasonably foreseeable by any "insured";
 that would cause a reasonable person to believe a "class 1 product recall" would result;
 - (6) Redistribution or replacement of the withdrawn products by like products or similar products or batches that are not defective products or substitutions;
 - (7) Loss or injury of reputation, customer faith or approval, or any costs incurred to regain customer market, or any other consequential damages;
 - (8) "Insured product" exceeding its designated shelf life; or
 - (9) Withdrawal of similar products or batches that are not defective, when a defect in another product or batch has been found.
4. We will make these payments regardless of fault; however, we will not pay expenses for any "circumstance," "claim" or "suit" otherwise excluded under this policy. Payment of "class 1 product recall expenses" is not an acknowledgment by us that a "circumstance," "claim" or "suit" is a covered loss under this insurance.
5. The Each Recall Class 1 Product Recall Expense Reimbursement Limit shown in the Declarations is the most we will pay for each reported "class 1 product recall." The Each Class 1 Product Recall Expense Reimbursement Aggregate limit shown in the Declarations is the most we will pay for all "class 1 product recall expenses" during the policy term. This limit is part of, not in addition to, the Policy Aggregate Limit of Insurance shown in the Declarations.

SECTION IV—COMMON POLICY EXCLUSIONS

In addition to any exclusions listed in **SECTION I—PRODUCTS-WORK HAZARD LIABILITY COVERAGE**, **SECTION II—LIFE SCIENCE PROFESSIONAL LIABILITY COVERAGE** and **SECTION III—SUPPLEMENTAL COVERAGES**, this insurance does not apply to:

A. ANTITRUST, CONSUMER FRAUD, OR UNFAIR COMPETITION

"Bodily injury," "property damage," "personal and advertising injury" and "professional services injury" based on, arising out of or in any way related to any actual or alleged:

- a. Antitrust violation, restraint of trade, price-fixing, or monopolistic practices, including, but not limited to violations of the Sherman Anti-Trust Act, the Clayton Act, or the Robinson-Patman Act (all as amended);

- b. Consumer fraud;
- c. False, deceptive, or unfair trade practices;
- d. Piracy;
- e. Unfair competition; or
- f. Violation of any consumer protection laws.

This exclusion does not affect our duty to defend an “insured” prior to determining, through the appropriate legal processes, that that “insured” is responsible for a criminal, fraudulent, malicious, dishonest or knowingly wrongful act, error or omission.

B. ASBESTOS

1. Any products containing “asbestos”; or
2. “Bodily injury,” “property damage,” “personal and advertising injury” or “professional services injury” arising out of any actual alleged or threatened:
 - a. Contaminative, pathogenic, toxic or other hazardous properties of asbestos;
 - b. Demand, order, request, regulatory or statutory requirement that any “insured” or others test for, monitor, clean up, remove, contain, treat, detoxify or neutralize, or in any way respond to, or assess the effects of asbestos; or
 - c. “Claim” or “suit” or proceeding by or on behalf of a governmental authority or others for any “damages,” “defense costs,” loss, cost or expense because of testing for, monitoring, cleaning up, removing, containing, treating, detoxifying or neutralizing, or in any way responding to, or assessing the effects of asbestos.

This exclusion applies whether or not the asbestos was at any time airborne as a fiber, particle or dust, contained in or formed a part of a product, structure or other real or personal property, carried on clothing, inhaled or ingested, or transmitted by any other means including its presence or use in any alloy, by-product, compound or other material waste.

C. BATCH, RELATED CLAIMS OR INTEGRATED OCCURRENCES AND OFFENSES

“Bodily injury,” “property damage,” “personal and advertising injury” or “professional services injury” covered under any “related claim” language in any other policy, including language in any other policy designed to cover “claims,” “related claims” or other events which commenced or occurred prior to the policy term, unless we specifically agree to provide coverage for such “claims,” products or work in an endorsement attached to this policy.

D. CRIMINAL, FRAUDULENT, MALICIOUS, DISHONEST OR KNOWINGLY WRONGFUL ACTS

“Bodily injury,” “property damage,” “personal and advertising injury” or “professional services injury” arising out of criminal, fraudulent, malicious, dishonest or knowingly wrongful acts, errors or omissions by an “insured.” However, this exclusion shall not apply to any “insured” who did not:

1. Personally commit;
2. Personally participate in;
3. Personally acquiesce to; or
4. Remain passive after having personal knowledge of any such acts, errors or omissions.

This exclusion does not affect our duty to defend an “insured” prior to determining, through the appropriate legal processes, that that “insured” is responsible for a criminal, fraudulent, malicious, dishonest or knowingly wrongful act, error or omission.

E. CROSS LIABILITY

Any "claim" or "suit" against any "insured" brought by the "Insured Entity" or on the "Insured Entity's" behalf.

F. INFRINGEMENT OF INTELLECTUAL PROPERTY RIGHTS

"Personal and advertising injury" or "professional services injury" based on or arising out of any actual or alleged assertion, infringement or violation by any person or entity, of any intellectual property rights, including, but not limited to the following:

1. A copyright, patent, trademark, intellectual design right, collective trade mark, certification mark or service mark or any similar such protections or rights (whether or not any of the foregoing are registered);
2. A trade secret or other type of formula, practice, process, design, instrument, pattern or compilation of information regarded by a business as confidential or proprietary;
3. Trade dress or any right protecting any interest in a name, symbol, slogan, style of doing business, or any similar such expression, likeness or idea; or
4. The use of another's name or product in the "Insured Entity's" e-mail address, domain name, social media application user name, metatag, or any other similar tactics to mislead another's potential customers.

This exclusion does not affect our duty to defend an "insured" prior to determining, through the appropriate legal processes, that that "insured" is responsible for infringement of intellectual property rights.

G. MEDICAL SERVICES

"Bodily injury," "property damage," "personal and advertising injury" or "professional services injury" based on, arising out of or in any way related to "medical services."

However, this exclusion does not apply to:

1. Dentists, emergency medical technicians, nurses, paramedics, or physicians employed by the "Insured Entity" to the extent that they are rendering first aid or emergency care;
2. Any "products-work hazard claim" made against a "clinical trial investigator," but only if the "clinical trial investigator" has not deviated from the written protocol of the "clinical trial"; or
3. "Bodily injury" based on, arising out of or in any way related to the failure to render "medical services," but only for:
 - a. "Bodily injury" caused by a defect, deficiency, inadequacy or dangerous condition in "insured product" to which this insurance applies;
 - b. "Bodily injury" arising from the service provided within the scope of and in accordance with the applicable written protocol of a "clinical trial" which this insurance applies;
 - c. "Bodily injury" caused by the failure to provide cardiopulmonary resuscitation or other first aid services;
 - d. "Bodily injury" caused by the failure to provide oxygen as a service or prescription; or
 - e. "Medical expenses" provided under **SECTION III—SUPPLEMENTAL COVERAGES**.

H. NUCLEAR

1. Under any Liability Coverage, to "bodily injury," "property damage" or "professional services injury," including all forms of radioactive contamination of property:

- a. With respect to which an “insured” under the policy is also an insured under a nuclear energy liability policy issued by Nuclear Energy Liability Insurance Association, Mutual Atomic Energy Liability Underwriters, Nuclear Insurance Association of Canada or any of their successors, or would be an insured under any such policy, but for its termination upon exhaustion of its limit of liability; or
 - b. Resulting from the “hazardous properties” of “nuclear material” and with respect to which:
 - (1) Any person or organization is required to maintain financial protection pursuant to the Atomic Energy Act of 1954, or any law amendatory thereof; or
 - (2) The “insured” is, or had this policy 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.
2. Under any Medical Expense Supplemental Coverage, to expenses incurred with respect to “bodily injury” resulting from the “hazardous properties” of “nuclear material” and arising out of the operation of a “nuclear facility” by any person or organization.
 3. Under any Liability Coverage, to “bodily injury” or “property damage,” including all forms of radioactive contamination of property resulting from “hazardous properties” of “nuclear material,” if:
 - a. The “nuclear material”: (a) is at any “nuclear facility” owned by, or operated by or on behalf of, an “insured”; or (b) has been discharged or dispersed therefrom;
 - b. 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
 - c. The “bodily injury” or “property damage,” including all forms of radioactive contamination of property 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 c. applies only to “property damage,” including all forms of radioactive contamination of property to such “nuclear facility” and any property threat.

I. PERFORMANCE DELAY

“Bodily injury,” “property damage,” “personal and advertising injury” or “professional services injury” based on or arising out of any actual or alleged delay in delivery of or failure to complete “insured product” or “insured work.”

However, this exclusion does not apply if the alleged delay in delivery of or failure to complete the “insured product” or “insured work”:

1. Is as a result of a “force majeure”;
2. Is not caused by the “Insured Entity’s” actions or failure to act; and
3. The agreement to provide “insured product” or “insured work” was entered into by the “Insured Entity” prior to the onset of the “force majeure.”

J. POLLUTION

1. “Bodily injury,” “property damage” or “professional services injury” arising out of the actual, alleged or threatened discharge, dispersal, seepage, migration, release or escape of “pollutants”:
 - a. At or from any premises, site or location which is or was at any time owned or occupied by, or rented or loaned to, any “insured.” However, this subparagraph does not apply to:

“Bodily injury” or “property damage” for which the “insured” may be held liable, if the “insured” is a contractor and the owner or lessee of such premises, site or location has been added to the “insured’s” policy as an additional insured with respect to the “insured’s” ongoing operations performed for that additional insured at that premises, site or location and such premises, site or location is not and never was owned or occupied by, or rented or loaned to, any insured, other than that additional insured;

- b. At or from any premises, site or location which is or was at any time used by or for any “insured” or others for the handling, storage, disposal, processing or treatment of waste;
 - c. Which are or were at any time transported, handled, stored, treated, disposed of, or processed as waste by or for:
 - (1) Any “insured”; or
 - (2) Any person or organization for whom the “insured” may be legally responsible;
 - d. At or from any premises, site or location on which any insured or any contractors or subcontractors working directly or indirectly on any “insured’s” behalf are performing operations if the “pollutants” are brought on to the premises, site or location in connection with such operations by such insured, contractor or subcontractor; or
 - e. At or from any premises, site or location on which any “insured” or any contractors or subcontractors working directly or indirectly on any “insured’s” behalf are performing operations if the operations are to test for, monitor, clean up, remove, contain, treat, detoxify or neutralize, or in any way respond to, or assess the effects of, “pollutants.”
2. Any “damages” or “defense costs” arising out of any:
- a. Request, demand, order or statutory or regulatory requirement that any “insured” or others test for, monitor, clean up, remove, contain, treat, detoxify or neutralize, or in any way respond to, or assess the effects of, “pollutants”; or
 - b. “Claim” or “suit” by or on behalf of a governmental authority for damages because of testing for, monitoring, cleaning up, removing, containing, treating, detoxifying or neutralizing, or in any way responding to, or assessing the effects of, “pollutants.”

However, this paragraph does not apply to liability for damages because of “property damage” that the insured would have in the absence of such request, demand, order or statutory or regulatory requirement, or such “claim” or “suit” by or on behalf of a governmental authority.

K. PRODUCT OR WORK SUPPORT

“Bodily injury,” “property damage,” “personal and advertising injury,” “data breach economic injury” or “professional services injury” arising out of any actual, alleged or threatened decision by any “insured” not to provide or support “insured product” or “insured work,” or to cease such provision or support.

L. WAR

“Bodily injury,” “property damage,” “personal and advertising injury,” “data breach economic injury” or “professional services injury” however caused, arising directly or indirectly, out of:

- 1. War, including undeclared or civil war;
- 2. Warlike action by a military force, including action in hindering or defending against an actual or expected attack, by any government, sovereign or other authority using military personnel or other agents; or
- 3. Insurrection, rebellion, revolution, usurped power, or action taken by governmental authority in hindering or defending against any of these.

However, this exclusion does not apply if there is any delay in delivery of or failure to complete the “insured product” or “insured work” as a result of a “force majeure” that is war or civil insurrection; and

1. Is not caused by the “Insured Entity’s” actions or failure to act; and
2. The agreement to provide “insured product” or “insured work” was entered into by the “Insured Entity” prior to the onset of the “force majeure.”

SECTION V—LIMITS OF INSURANCE

A. The Limits of Insurance shown in the Declarations and the rules below fix the most we will pay regardless of the number of:

1. “Insureds”;
2. “Claims” or “suits” made or brought; or
3. Persons or organizations making “claims.”

B. The Products-Work Hazard Liability Aggregate Limit of Insurance is the most we will pay for the sum of “damages” and “defense costs” under Products-Work Hazard Liability.

The Life Science Professional Liability Aggregate Limit of Insurance is the most we will pay for the sum of “damages” and “defense costs” under Life Science Professional Liability.

The Policy Aggregate Limit of Insurance is the most we will pay for the sum of “damages” and “defense costs” under:

- a. Products-Work Hazard Liability;
- b. Life Science Professional Liability; and
- c. Supplemental Coverages, unless otherwise specified.

C. Subject to subsection **B.** above, the Products-Work Hazard Each Claim Limit is the most we will pay because of all “bodily injury,” “property damage” and “personal advertising injury” arising out of any one “claim” or “suit.”

D. Subject to subsection **B.** above, the Life Science Professional Liability Each Claim Limit is the most we will pay because of all “professional services injury” arising out of any one “claim” or “suit.”

E. If, during the policy term, either the “Insured Entity” or we declare in writing to the other that a “claim” or “suit” is likely to give rise to subsequent “related claims,” then such “claim” or “suit” and all such subsequent “related claims,” shall be deemed a single “claim” or “suit.” If such a declaration is made, the Limits of Insurance applicable to the “claim” or “suit” are the limits in effect for the policy term in which the written declaration was made.

F. “Defense costs” will be paid first, will reduce and may exhaust the Limits of Insurance.

G. The Limits of Insurance apply separately to each consecutive annual period and to any remaining period of less than twelve (12) months, starting at the beginning of the policy term shown in the Declarations, unless the policy term is extended after issuance for an additional period of less than twelve (12) months. In that case, the additional period will be deemed part of the last preceding period for purposes of determining the Limits of Insurance.

SECTION VI—DEDUCTIBLE

A. Our obligation under this insurance to pay “damages” or “defense costs” on behalf of the “insured” applies only to the amount of “damages” and “defense costs” in excess of any deductible amounts shown in the Declarations. The Limits of Insurance are in excess of and not reduced by the deductible. This deductible applies to each “claim” or “suit” unless otherwise specified. No deductible applies to any payments made under Supplemental Coverages.

The maximum deductible for all “damages” and “defense costs” during the policy term is the Deductible Aggregate, if any, shown in the Declarations.

- B. The terms of this insurance apply irrespective of the application of the deductible amount.
- C. We may pay any part or all of the deductible amount to effect settlement of any “claim” or “suit” and, upon notification of the action taken, the “Named Insured” shall promptly reimburse us for such part of the deductible amount as has been paid by us.

SECTION VII—DEEMED MADE

- A. A “data breach,” injury, damage, or “circumstance,” will be deemed made at the earliest time when an “executive officer” of the “Insured Entity”:
 - 1. Becomes aware or would have been aware that the “circumstance,” injury, damage, or “data breach” has happened or has begun;
 - 2. In the case of a civil proceeding in a court of law or equity, or arbitration, on the date of service upon or other receipt by the “Insured Entity” of a complaint against the “Insured Entity” in such a proceeding or arbitration; or
 - 3. At the time of an “advisory memorandum,” “class 1 product recall” or “boxed warning” arising from the “insured product” or “insured work.”
- B. An “occurrence,” offense or “wrongful act” will be deemed to have occurred on the earliest date:
 - 1. “Insured product” or “insured work” giving rise to such “occurrence,” offense or “wrongful act” was first ingested, implanted, applied or otherwise used;
 - 2. A “claim” or “suit” is made alleging “bodily injury,” “property damage,” “personal and advertising injury” or “wrongful act” resulting from “insured product” or “insured work”;
 - 3. A professional medical opinion is rendered that provides a basis for a “claim” or “suit” under the coverage provided;
 - 4. “Medical expenses” are incurred as a result of “bodily injury”;
 - 5. Death occurs as a result of exposure to “insured product” or “insured work”;
 - 6. Of removal or replacement of “insured product”;
 - 7. An “advisory memorandum,” “class 1 product recall” or “boxed warning” is issued.
- C. A “claim,” or “suit” will be deemed made at the earliest of the following:
 - 1. Notice of such “claim” or “suit” is received and recorded by any “Insured Entity”;
 - 2. Notice of such “claim” or “suit” is received and recorded by us; or
 - 3. At the time of an “advisory memorandum,” “boxed warning” or “class 1 product recall” arising from or related to the “insured product” or “insured work.”
- D. Deemed or deemed made means with respect to a specific person, known by or that would have been known from the standpoint of a reasonable person in the position of such person; or with respect to a specific organization, known by or that would have been known from the standpoint of a reasonable person in the position of any of such organization’s “executive officer.”
- E. Deemed made does not include a report in connection with an “adverse event” as described under the provisions of **SECTION VIII—COMMON CONDITIONS** titled **ADVERSE EVENTS REPORTING**.
- F. All “claims” or “suits” made by the same person or organization and arising out of the same “incident” will be deemed made at the time the first of those “claims” or “suits” is made against any “insured.”

SECTION VIII—COMMON CONDITIONS

A. ADVERSE EVENT REPORTING

Reporting of an “adverse event” to a government or regulatory authority, in itself, does not constitute:

1. A conclusion that “insured product” or “insured work” caused or contributed to such event;
2. An admission or assumption of liability;
3. Knowledge of an “incident,” injury or damage (whether or not any of the forgoing is a “circumstance”) that would be expected to result in a payment of insurance;
4. A conclusion that injury was expected or intended as described **SECTION I—PRODUCTS-WORK HAZARD LIABILITY COVERAGE**, subsection **B. PRODUCTS-WORK HAZARD EXCLUSIONS**, paragraph 7. **Expected or Intended Injury**; or
5. Compliance with the notice requirements described under **DUTIES IN THE EVENT OF AN ADVISORY MEMORANDUM, CLASS 1 PRODUCT RECALL OR BOXED WARNING**

B. ARBITRATION

We are entitled to exercise all of the “Insured Entity’s” rights in the choice of arbitrators and in the conduct of any arbitration proceedings, except when the proceeding is between us and the “insured.”

After the “insured” reports a “claim” or “suit” and the “insured” has the right under any contract to either reject or demand arbitration or other alternative dispute resolution process, the “insured” shall only do so with our written consent.

The “insured” agrees to be bound by the following arbitration rules in the event a dispute arises between the “insured” and us, our employees, agents or representatives with respect to coverage, any condition of this policy, or any other matter arising out of or related to this policy or the relationship between us, our employees, agents or representatives and the “insured” under this policy.

1. The parties intend to simplify the dispute process by the non-judicial resolution of any dispute concerning their relationship and make it possible for us to reduce our litigation costs by resolving all disputes through arbitration in Arizona.
2. The matter shall be resolved by binding arbitration before three privately selected arbitrators pursuant to the Federal Arbitration Act. If a dispute subject to arbitration hereunder should arise, either party may make a demand for arbitration by filing a demand in writing with the other party. There shall be three arbitrators, one named in writing by each of the parties within ten days after demand for arbitration is given and a third chosen by the two appointed arbitrators. The arbitrators appointed by the “insured” and us need not be independent and may be lawyers for the parties. The third arbitrator must be an individual with experience in the insurance industry. Should either party refuse or neglect to join in the appointment of the arbitrator(s) or to furnish the arbitrator(s) with any papers or information demanded, the appointed arbitrator(s) is/are empowered by both parties to proceed ex parte.
3. The arbitrators shall apply the law of the State of Arizona.
4. Each party shall appoint and pay for any counsel appointed to represent it in such arbitration, unless otherwise provided by law.

This subsection is not to be construed to give a right of action against us, our employees, agents or representatives by anyone who is not an “insured” under this policy.

C. ANNUAL RATING AND LIMIT

If this policy is issued or extended for a period in excess of one year:

1. The Premium may be revised on each annual anniversary in accordance with our rates and rules at the time; and
2. The Limits of Insurance provided in the Declarations applies for the entire policy term and will not be refreshed or reinstated.

D. ASSIGNMENT

The assignment of the interest of any “insured” under this policy is prohibited and shall not be binding unless and until our consent is endorsed herein.

E. AUDIT

1. The premium for this policy is auditable as shown in the Declarations. Therefore, if:
 - a. Regular Audit is shown in the Declarations, then at the close of each audit period we will compute the earned premium for that period. If the earned premium is either less than or greater than the deposit premium shown in the Declarations, then a final premium adjustment endorsement will be issued; or
 - b. Threshold Audit Percentage is shown in the Declarations, then we will follow the audit procedure outlined in subparagraph a. except there will be no final premium adjustment endorsement issued unless the audited exposure deviates from the estimated exposure by more than the Threshold Audit Percentage indicated.
2. All premium due will be subject to the minimum earned premium.
3. We will return any excess premium to the “First Named Insured,” subject to paragraph 1. above. Any additional audit premium is due and payable upon notice to the “First Named Insured.” Failure to pay the audit premium due under this policy or any other in-force policy issued to the “First Named Insured” will be deemed a breach of contract. This policy and any other in-force policy issued to the “First Named Insured,” will then be subject to cancellation for non-payment of premium.
4. We may examine and audit the “Insured Entity’s” books and records as we may reasonably direct during the policy term and extensions thereof and within three years after the final termination of the policy as far as they relate to the subject matter of this policy.
5. The “Insured Entity” shall maintain records of such information as it is necessary for auditable premium computation and shall send copies of such records to us at the end of the policy term and at such times during the policy term as we may direct. Subsequent to audit by us, the “Insured Entity” shall forward to us any additional premiums warranted by such audit.

F. BANKRUPTCY

Bankruptcy or insolvency of the “Insured Entity” or of the “Insured Entity’s” estate will not relieve us of our obligations under this policy.

In the event of the “Insured Entity’s” bankruptcy, insolvency, receivership or any refusal or inability of the “Insured Entity” to pay “damages” and “defense costs” to which this policy applies, the insurance afforded by this policy shall not replace or supplement the deductible or Self-Insured Retention, but shall apply in the same manner as though the “Insured Entity” were willing and able to pay. In no event shall we assume the “Insured Entity’s” responsibilities or obligations.

G. CANCELLATION OR NONRENEWAL

1. The “First Named Insured” may cancel this policy at any time by surrendering the policy to us or by mailing or electronic mailing to us written notice stating when the cancellation is to take effect.

2. We may cancel this policy at any time by mailing to the “First Named Insured” at the last known address shown in the policy written notice of cancellation at least:
 - a. Twenty (20) days before the effective date of cancellation if we cancel for nonpayment of premium; or
 - b. Ninety (90) days before the effective date of cancellation if we cancel for any other reason.
 - c. For policies in effect for less than ninety (90) days, the policy may be cancelled by mailing or delivering to the “First Named Insured” written notice of cancellation at least thirty (30) days before the effective date of cancellation.
3. If we cancel the policy, we will refund the pro rata unearned premium. If the “First Named Insured” cancels the policy, we will refund ninety percent (90%) of the pro rata unearned premium.
4. If we decide not to renew this policy, we will mail or deliver to the “First Named Insured’s” last known address shown in the policy written notice of the nonrenewal at least ninety (90) days before the expiration date of the policy term.
5. Proof of mailing shall be sufficient proof of notice.

H. CHANGES

This policy can only be changed by request of the “First Named Insured” and by a written endorsement that becomes part of the policy.

I. CHANGE OF STATUS OF INSURED

1. In the event of an acquisition of the “First Named Insured,” this policy shall automatically and without any notification from us, terminate effective as of the date of such acquisition unless:
 - a. We are notified in writing of the acquisition prior to the acquisition effective date;
 - b. We agree in writing to continue the policy beyond the effective date of acquisition;
 - c. The “First Named Insured” accepts any special terms, conditions and exclusions; and
 - d. The “First Named Insured” pays any additional premium charge required by us.
2. In the event the “First Named Insured” merges with an entity, acquires an entity (including its subsidiaries); purchases assets or acquires liabilities and:
 - a. The revenue of the merged or acquired entity or such assets or liabilities immediately prior to the date of completion of the acquisition do not exceed ten percent (10%) of the “First Named Insured’s” annual revenues or assets as specified in its most recent “application” for insurance provided to us;
 - b. The business operations of the merged or acquired entity are of similar nature to those of the “First Named Insured” as specified in recent “application” to us; and
 - c. The operations of the merged or acquired entity are primarily located in the same “coverage territory” as the “First Named Insured” or any of its subsidiaries;

this policy will automatically cover the merged or acquired entity from the date of completion of such merger or acquisition, but only for “incidents” for which this insurance applies that first occur after the date of completion of such merger or acquisition and then only for a period of sixty (60) days or until the end of the policy term, which is earlier. Coverage will not continue beyond the sixty (60) day period immediately following the completion of the merger or acquisition unless we specifically agree, in writing, to add such entity to the policy by endorsement, specifying the terms and conditions of its coverage.

Coverage provided under subsection **1.2.** is excess over any valid and collectable insurance available to the “insured” regardless of whether the other insurance is written under the same terms and conditions.

3. Any additional premium calculated as a result of the merger or acquisition is due and payable.
4. In the event any entity ceases to be a subsidiary, such entity shall cease to be an “insured” and all coverage under this policy will cease for the entity effective on the date such entity ceased to be a subsidiary unless:
 - a. We are notified in writing of such cessation prior to the effective date thereof;
 - b. We agree in writing to continue coverage for such subsidiary;
 - c. The “First Named insured” accepts any special terms, conditions and exclusions; and
 - d. The “First Named Insured” pays any additional premium charge required by us.
5. A subsidiary includes any entity in which the “insured” has a managing controlling interest derived from:
 - a. Owning interests representing more than fifty percent (50%) of the voting, appointment or designation power for the selection of a majority of:
 - (1) The Board of Directors of a corporation;
 - (2) The management committee members of a joint venture;
 - (3) The managing or general partners of a partnership; or
 - (4) The members of the management board of a limited liability company; or
 - b. Having the right, pursuant to the “First Named Insured’s” by-laws, charter, operating agreement, Partnership Agreement or similar documents, to elect, appoint or designate:
 - (1) A majority of:
 - (a) The Board of Directors of a corporation;
 - (b) The management committee of a joint venture; or
 - (c) The members of the management board of a limited liability company; or
 - (2) The general partners of a limited partnership or one or more managing partners of a partnership other than a limited partnership.

J. COMPLIANCE BY INSUREDS

We have no duty to provide coverage under this policy unless the “Named Insured” has fully complied with all of the terms and conditions of this policy.

K. COMPLIANCE WITH TRADE AND ECONOMIC SANCTIONS

This insurance does not apply to the extent that trade or economic sanctions or other laws or regulations prohibit us from providing insurance.

L. CONFORMANCE WITH STATUTES

Any terms of this insurance which conflict with the applicable statutes of the state in which this policy is issued are amended to conform to such statutes.

M. CURRENCY

The limits, deductibles, expenses, retentions, premiums and “damages” and “defense costs” of this policy are payable in United States of America currency unless otherwise specified.

N. PAYMENT OF DEDUCTIBLE

Any applicable deductible shall be paid by the "First Named Insured," or upon its failure to pay, jointly and severally by all "Insured Entities," or anyone on the "Insured Entity's" behalf.

O. DEFENSE

1. We will pay reasonable attorney fees and necessary litigation expenses to defend:
 - a. The "insured"; and
 - b. If applicable, the indemnitee of the "insured," provided the obligation for the cost of the defense of such indemnitee has been assumed by such "insured" in an "insured contract."
2. We will designate or, at our option, approve counsel to defend the "claim" or "suit." If a "claim" or "suit" is subject to arbitration or mediation, we shall be entitled to exercise all the "insured's" rights in the choice of arbitrators or mediators and in the conduct of any arbitration or mediation proceedings involving such "claim" or "suit."

P. DISCLOSURE, REPRESENTATION AND ENTIRE CONTRACT

We have issued this insurance based upon representations made by the "Insured Entity" and in our reliance of such representations. By acceptance of this policy, the "Insured Entity" agrees that:

1. All information and statements provided to us by the "Insured Entity" are true, accurate and complete and shall be deemed to constitute material representation made by all "insureds."
2. This policy and endorsements together with the completed and signed "application" embody all of the agreements and shall constitute the entire contract between the "insureds" and us.
3. The willful or intentional misrepresentation of any material matter by the "Insured Entity" or its agent will render this policy null and void and relieve us from all liability herein.
4. Unintentional failure of an "employee" of the "insured" to disclose a hazard or other material information will not violate this condition, unless an "executive officer" (whether or not an "employee") of any "insured" knows about such hazard or other material information.

Q. DUTIES IN THE EVENT OF AN ADVISORY MEMORANDUM, CLASS 1 PRODUCT RECALL OR BOXED WARNING

1. Notice to Us
 - a. Any "circumstance" that is an "advisory memorandum," "class 1 product recall" or "boxed warning" must be reported to us at the time of each such "advisory memorandum," "class 1 product recall" or "boxed warning."
 - b. Any "incident" that leads the "insured" to believe a "class 1 product recall" is likely to occur, whether or not the "class 1 product recall expenses" are likely to exceed the deductible shown in the Declarations, must be reported to us.

Notice should include:

- (1) How, when and where the "incident" took place;
- (2) The names and addresses of injured persons or witnesses to the "incident" that may lead to a "class 1 product recall"; and
- (3) The estimated "class 1 product recall expenses."

R. DUTIES IN THE EVENT OF AN INCIDENT, CLAIM OR SUIT

1. Knowledge of an Incident:
 - a. The “insured” must see to it that we and any other insurers are notified of as soon as practicable of any “incident” that may result in a “circumstance,” “claim” or “suit.”
 - b. Knowledge of an “incident” by an agent or “employee” of the “insured” will not constitute knowledge by the “insured,” unless an “executive officer” (whether an “employee” or not) of any “insured” knows about such “incident.”
 - c. Notice should include:
 - (1) How, when and where the “incident” took place;
 - (2) The names and addresses of any injured persons and witnesses; and
 - (3) The nature and location of any injury or damage arising out of the “incident.”
 - d. Notice of an “incident” is not notice of a “circumstance,” “claim” or “suit.”
 - e. The “insured” must promptly forward to us all documents that the “insured” receives in connection with the “incident.”
2. Knowledge of a “Claim” or “Suit”
 - a. If a “claim” or “suit” is made against any “insured,” the “Insured Entity” must:
 - (1) Immediately record the specifics of the “claim” or “suit” and the date received;
 - (2) Notify us and other insurers as soon as practicable; and
 - (3) See to it that we receive written notice of the “claim” or “suit” as soon as practicable, but no later than ninety (90) days after the end of the policy term, or if purchased, the end of the Extended Reporting Period, in accordance with the provisions of **SECTION VIII—COMMON CONDITIONS**, subsection **T. EXTENDED REPORTING PERIODS**.
 - b. The “insured” must:
 - (1) Immediately send us copies of any demands, notices, summonses or legal papers received in connection with the “claim” or “suit”;
 - (2) Authorize us to obtain records or other information;
 - (3) Cooperate with us or other insurers in the:
 - (a) Investigation or settlement of the “claim” or “suit”; or
 - (b) Defense against the “claim” or “suit”;
 - (4) Assist us, upon our request, in the enforcement of any right against any person or organization that may be liable to the “insured” because of loss to which this insurance may also apply;
 - (5) Attend hearings and trials and assist in securing evidence and obtaining the attendance of witnesses; and
 - (6) Refuse, except solely at the “insured’s” own cost, to voluntarily, without our written approval, make any payment, admit liability, assume any obligation or incur any expense. However, this requirement does not apply to coverage provided under **SECTION III—SUPPLEMENTAL COVERAGES** subsection **C. MEDICAL EXPENSE REIMBURSEMENT**.
3. Any notice to us under this condition must be in writing and addressed to our claim department.

S. ELECTION OF COVERAGE

If more than one coverage section of this policy applies to the same “circumstance,” “claim” or “suit,” only the coverage section most applicable to that type of “circumstance,” “claim” or “suit” shall apply. We have the right to select the applicable coverage section. We will not pay more than the Limit of Insurance of the one individual coverage section as selected by us or the actual amount of “damage” or “defense costs,” whichever is less.

T. EXTENDED REPORTING PERIODS

1. An Extended Reporting Period is not available if this policy is nonrenewed or cancelled due to:
 - a. Non-payment of premium, a Self-Insured Retention or deductible; or
 - b. Failure to comply with the terms and condition of this policy.
2. If the policy is non-renewed or cancelled for any other reason, we will automatically provide a Basic Extended Reporting Period at no additional premium. The Basic Extended Reporting Period starts with the date coverage under this policy ends and lasts for:
 - a. Ninety (90) days for “claims” or “suits”; and
 - b. Five years for “claims” or “suits” that were reported to us as a “circumstance” during the policy term, but only;

if no other insurance is purchased by the “Insured Entity” to replace this policy or the other insurance would apply, but for the exhaustion of the applicable Limits of Insurance.
3. The Basic Extended Reporting Period may be substituted by a Supplemental Extended Reporting Period by endorsement, provided that within ninety (90) days following the end of the policy term or effective date of cancellation:
 - a. The “First Named Insured” makes a written request for a Supplemental Extended Reporting Period; and
 - b. Pays the required additional premium.
4. The required additional premium for a Supplemental Extended Reporting Period is fully earned on the effective date of the Supplemental Extended Reporting Period.
5. Only one Supplemental Extended Reporting Period will be made available, and it will be shared by all qualifying interests under this policy. No separate Basic or Supplemental Extended Reporting Period will be provided to any specific person or organization.
6. Basic and Supplemental Extended Reporting Periods:
 - a. May not be cancelled once in effect; and
 - b. Do not:
 - (1) Extend the policy term or change the scope of coverage to which this insurance applies;
 - (2) Increase or reinstate the Limits of Insurance; and
 - (3) Apply to any “damages,” loss, cost, “defense costs” or expense covered under any other insurance, including any subsequent insurance policies purchased by the “Insured Entity.”

U. FIRST NAMED INSURED PROVISIONS

1. The “First Named insured” is responsible:
 - a. To act on behalf of any person or organization (other than us) having rights or duties under this policy; and

- b. If any of the other insurance does not permit contribution by equal shares, then we will contribute by limits. Under this method, each insurer's share is based on the ratio of its applicable limits of insurance to the total applicable limits of insurance for all insurers.
- 5. If any "claim" or "suit" under this policy is also covered by one or more policies issued by us or by any of our affiliated or subsidiary insurance companies, to:
 - a. The "Named Insured"; or
 - b. Any entity or person who:
 - (1) Controls;
 - (2) Is controlled by; or
 - (3) Is affiliated by common control with;the "Named Insured";

then the maximum applicable Limits of Insurance available under all policies shall not be the total of the limits of insurance for those policies, but rather shall not exceed the highest applicable Limits of Insurance under any one policy. Each policy's share in the loss is based on the ratio of its applicable limits of insurance to the total applicable limits of insurance for all policies.

Z. PREMIUM

All premium charges under this policy will be computed according to the rules, rates and rating plans that apply at the effective date of the current policy term, subject to the provisions of subsection **C. ANNUAL RATING AND LIMIT.**

AA. PRIMARY AND NON-CONTRIBUTORY CLAUSE

This insurance is primary to and will not seek contribution from any other insurance available to a person or organization who is an "insured" under this policy provided that the "Insured Entity" has agreed in writing to that person or organization that this insurance is primary and would not seek contribution from any other insurance available to such person or organization.

However, this does not apply to Supplemental Coverages that are specifically stated to be excess over any other insurance.

BB. RIGHT TO CLAIM INFORMATION

A list or other record of each "incident," "circumstance," "claim" or "suit" reported to us and not previously reported to any other insurer, is available to the "First Named Insured." We will include the date and brief description of the "incident," "circumstance," "claim" or "suit" if that information was included in the notice received by us. Additionally, a summary by policy year of payments made and amounts reserved, stated separately, may also be provided to the "First Named Insured."

CC. SEPARATION OF INSUREDS

Except with respect to the Limits of Insurance, and any rights or duties specifically assigned in this policy to the "First Named Insured," this insurance applies:

1. As if each of the "Insured Entities" were the only "Insured Entity"; and
2. Separately to each "insured" against whom a "claim" is made, or "suit" is brought.

DD. SUBROGATION

If any "insured" has rights to recover all or part of any payment we have made under this policy, those rights are transferred to us. The "insured" must do nothing to impair those rights. At our request, the "insured" will bring "suit" or transfer those rights to us and help us enforce them.

EE. TRANSFER OF RIGHTS AND DUTIES

The “Insured Entity’s” rights and duties under this policy may not be transferred without written consent from us. However, in the event of the “First Named Insured’s” death, those rights and duties will be transferred to their legal representative, but only while acting within the scope of duties as their legal representative, or to anyone having temporary custody of their property until their legal representation is appointed.

FF. WAIVER OF RIGHTS OF RECOVERY

We will waive the right of recovery we would otherwise have against another person or organization for payments we make under this policy, provided the “insured” has waived their rights of recovery against such person or organization in an “insured contract.”

To the extent that the “insured’s” rights to recover all or part of any payment made under this insurance have not been waived, those rights are transferred to us. The “insured” must do nothing to impair those rights. At our request, the “insured” will bring “suit” or transfer those rights to us and help us enforce them.

SECTION IX—DEFINITIONS

A. “Adverse event” includes any:

1. Outcome of the following types, regardless of whether or not the outcome is expected or intended:
 - a. Congenital anomaly or birth defect;
 - b. Death;
 - c. Disability or incapacity;
 - d. Hospitalization;
 - e. Life threatening disease, injury or sickness;of any person;
2. Intervention to prevent any outcome described in paragraph 1. above;
3. Malfunction of the “insured product” that may give rise to any outcome described in paragraphs 1. or 2. above; or
4. Condition that may give rise to any outcome described in paragraphs 1., 2. or 3. above, requiring notification to a governmental or regulatory authority.

B. “Advertisement” means a notice that is broadcast or published to the general public or specific market segments about the “insured’s” goods, products or services for the purpose of attracting customers or supporters.

“Advertisement” includes:

1. Notices that are published including material placed on the Internet or on similar electronic means of communication; and
2. That part of a website that is about the “Insured Entity’s” goods, products or services for the purposes of attracting customers or supporters.

C. “Advisory memorandum” means a written communication issued by the “Insured Entity” or on its behalf to healthcare professionals, customers, product users, suppliers, vendors or the public at large informing them of an actual or alleged defect or deficiency in an “insured product” or in its labeling.

D. “Application” means all signed applications for any policy in an uninterrupted series of policies issued by us or any affiliate of ours. “Application” also includes any materials submitted or required to be submitted.

- E. "Auto" means a land motor vehicle, trailer or semi-trailer designed for travel on public roads, including any attached machinery or equipment. "Auto" does not include "mobile equipment."
- F. "Biological products" means any vaccine, blood or blood component, allergenics, somatic cells, gene therapies, tissues or recombinant therapeutic proteins product derived from natural sources that is:
 1. Recognized in the United States National Formulary, the Federal Food, Drug and Cosmetic Act, Public Health Services Act or any provincial formulary, any supplement to any of these or their foreign equivalent;
 2. Intended for use in the diagnosis, cure, mitigation, treatment or prevention of injury, sickness or disease and which affects the structure or any function of the body; or
 3. A component of any product described above.

However, "biological product" does not include any "pharmaceutical drug," "medical device," "nutraceutical," food or beverage.

- G. "Bodily injury" means physical bodily injury, sickness or disease (including resulting death) sustained by a person. "Bodily injury" also means:
 1. Mental injury, mental anguish or shock sustained by that person as a result of such "bodily injury," sickness or disease; and
 2. "Bodily injury," sickness, disease, mental injury, mental anguish or shock sustained by a spouse, "domestic partner" or immediate family member of that person as result of such "bodily injury."
- H. "Boxed warning" means any notice required by the Food and Drug Administration pursuant to 21 CFR 201 or its foreign equivalent.
- I. "Care, custody or control property damage expense" means reasonable costs incurred as a result of "property damage" to the following property that is in an "insured's" care, custody or control:
 1. Goods or products held by an "insured" or on an "insured's" behalf for sale or entrusted to the "insured" for safekeeping or storage;
 2. Goods or products on an "insured's" premises for the purpose of performing operations on such goods or products by an "insured" or on an "insured's" behalf; or
 3. Goods or products of others while "insured work" is being performed on such goods or products.
- J. "Circumstance" means a matter from which an "executive officer" reasonably expects that facts as established by direct evidence would result in any payment under this policy.

The following are considered "circumstances":

1. Adjustment, disposal, inspection, recall, removal, repair, replacement or suspension or withdrawal from use, whether voluntary or otherwise, of "insured product" or any good or product that incorporates "insured product";
2. Governmental or regulatory investigation related to a "clinical trial," "insured product" or "insured work";
3. Investigation by any governmental or regulatory authority of any "clinical trial contractor" or other person or organization responsible for the conduct of a "clinical trial";
4. Notification by any governmental or regulatory authority, consumer, contractor other person or organization of a known or suspected defect, deficiency, inadequacy or dangerous condition in "insured product" or "insured work";
5. Physical injury to or loss of use of any facility that impairs the ability to conduct a "clinical trial" or to manufacture, sell, handle, distribute or dispose of "insured product" or to perform "insured work"; or

6. Suspension or termination of a “clinical trial” for any reason.
- K.** “Claim” means a demand for monetary damages or non-monetary services and includes any “professional liability claim.” A “claim” does not include a “circumstance.”
- L.** “Class 1 product recall” means removal or correction of an “insured product” by the “Insured Entity,” where the “Insured Entity,” the United States Food and Drug Administration or any foreign equivalent has determined that the “insured product” creates a reasonable probability that the use of or exposure to such “insured product” will cause serious adverse health consequences or death.
- M.** “Class 1 product recall expenses” means the following expenses incurred as a result of a “class 1 product recall” of “insured products” that have been physically relinquished to others:
1. Communication costs incurred to announce the withdrawal, including, but not limited to:
 - a. Telephone, radio, television, and internet announcements; and
 - b. Production costs of the announcements, such as printing costs, stationary, envelopes and postage;
 2. Costs incurred to transport “insured product” from any purchaser, distributor or user, to locations designated by the “insured”; or
 3. Costs incurred to transport the “insured’s” “employees” to any purchaser, distributor or user in order to effectuate reasonable and necessary on-site repairs.
- N.** “Clinical trial” means an organized study, test or protocol that uses subjects to establish the effectiveness, bioequivalence or safety of:
1. “Insured products”; or
 2. Products of the “insured’s” clients when the “insured” is a “Contract Research Organization.”
- O.** “Clinical trial consultant” means any medical intern, resident, technician, nurse, physician or other medical professional, who provides advice to a “clinical trial investigator.”
- P.** “Clinical trial consultant services” means:
1. Professional service, advice or demonstration of procedures in connection with clinical, laboratory, or research testing activities, within the scope of and in accordance with the applicable written protocol of a “clinical trial.”
 2. The planning, monitoring or review of “clinical trials.”
- Q.** “Clinical trial investigator” means an individual who conducts a “clinical trial” or provides services in connection with “clinical trials.”
- R.** “Contract research organization” means any entity that provides “professional services” to the “biological product,” pharmaceutical and drug, or “medical device” industries in connection with clinical research or “clinical trials” of a “life science product.”
- S.** “Coverage territory” means:
1. United States of America (including its territories and possessions), Puerto Rico and Canada;
 2. All other parts of the world if the injury or damage arises out of:
 - a. Goods or products made or sold by the “insured” in the territory described in paragraph 1. above; or
 - b. The activities of an “insured” whose domicile is in the territory described in paragraph 1. above, but is away for a short time on the “insured’s” business;

provided the “insured’s” legal obligation to pay “damages” is determined in a “suit” on the merits, in the territory described in paragraph 1. above or in a settlement to which we agree.

- T. “Crisis Mitigation Expenses” means reasonable expenses incurred by the “insured” in an effort to minimize the potential harm to or maintain and restore public confidence in the “Insured Entity” arising from a “circumstance,” “claim” or “suit.”

“Crisis mitigation expenses” does not include:

1. Compensation, fees, costs, benefits, overhead, charges or expenses of any “insured” or any “employee”;
2. Expenses incurred to comply with any governmental or regulatory requirement;
3. “Class 1 product recall expenses”;
4. “Data breach expenses”;
5. “Medical expenses”; or
6. “Damages,” “defense costs” or any other expenses that are payable on behalf of or to the “Insured Entity” under this policy or any other valid and collectible insurance.

- U. “Damages” means judgments, awards and settlements, provided any settlement is made with our prior written consent. “Damages” does not include:

1. Fees, costs and expenses paid or incurred by or on behalf of the “insured,” no matter whether sought as restitution of specific funds, forfeiture, financial loss, set-off or otherwise, and injuries that are a consequence of any of the foregoing;
2. Civil or criminal fines, sanctions, penalties or forfeitures, whether pursuant to law, order, ordinance, regulation or statute;
3. The multiplied portion of multiplied awards imposed pursuant to any law, order, ordinance, regulation or statute requiring such awards;
4. Injunctive or declaratory relief;
5. Any amount that is not insurable under any applicable law, order, ordinance, regulation or statute;
6. Any amounts for which an “insured” is legally obligated due to an act, error or omission in knowing violation of any written contract or agreement;
7. Plaintiff’s attorney fees associated with any of the above;
8. “Class 1 product recall expenses”;
9. “Crisis mitigation expenses”;
10. “Data breach expenses”; or
11. “Medical expenses.”

Notwithstanding paragraph 5. above, “damages” shall include punitive and exemplary damages, subject to other terms, conditions, exclusions and Limits of Insurance of this policy. Enforceability of this paragraph shall be governed by such applicable law that most favors coverage for such punitive or exemplary damages and has a substantial relationship to the “insureds,” the policy and the “claim” or “suit.”

- V. “Data Breach” means the unintentional:

Disclosure of or failure to protect “protected personal information” from access or use by any person or entity not authorized to have access or use the “protected personal information” provided that:

1. The disclosure of, access to or use of such “protected personal information” is prohibited by:
 - a. A privacy law, order, ordinance, regulation or statute in effect at the time of the “data breach”; or
 - b. An “insured contract” executed prior to the “data breach; and
 2. The parties to the “insured contract” or “protected persons” have not authorized the disclosure, access or use.
- W.** “Data Breach Economic Injury” means monetary “damages” sustained directly by an “insured’s” client or “protected person.”
- X.** “Data Breach Expense” means the following expenses incurred in an effort to minimize the potential harm to the “Insured Entity” arising out of a “data breach”:
1. Reasonable and necessary costs to engage a forensic consultant to investigate the cause and extent of a “data breach”;
 2. Reasonable and necessary costs to engage a public relations consultant to provide reputational management services on the “Insured Entity’s” behalf;
 3. Reasonable and necessary costs to provide community outreach and news media notification concerning a “data breach”;
 4. The following reasonable and necessary costs to comply with the notification requirements of any applicable privacy or breach of privacy law, order, ordinance, regulation or statute, due to a “data breach”:
 - a. Fees charged by legal counsel to determine the applicability of such law, order, ordinance, regulation or statute; and
 - b. The costs incurred to fulfill the notification requirements of those laws, orders, ordinances, regulations or statutes.
 5. The costs incurred to notify parties affected by the “data breach” who are not required to be notified under such laws, orders, ordinances, regulations or statutes may be reimbursed at our sole discretion.
- Y.** “Defense costs” means:
1. Fees charged by attorneys designated by us or by the “insured” with our prior written consent;
 2. All other reasonable and necessary fees, costs and expenses resulting from the investigation, adjustment, defense and appeal of a covered “claim” or “suit” if incurred by us, or by the “insured” with our prior written consent, including, but not limited to, premiums for any appeal bond, attachment bond or similar bond, but without any obligation of us to apply for or furnish any such bond;
 3. Prejudgment interest awarded against the “Insured Entity” on that part of a judgment we pay. If we make an offer to pay the applicable Limit of Insurance, we will not pay any prejudgment interest based on that period of time after such offer; or
 4. Interest on the full amount of a judgment that accrues after entry of the judgment and before we have paid, offered to pay or deposited in court the part of the judgment that is within the applicable Limit of Insurance.

However, “defense costs” does not include:

1. Any fees, costs or expenses that are not attributed to the processing of a specific insurance “claim” or “suit”;

- 2. "Crisis mitigation expenses"; or
 - 3. "Data breach expenses."
- Z.** "Domestic partner" means any person qualifying as such under any applicable law, order, ordinance, regulation or statute or under the "Insured Entity's" employee benefit plans.
- AA.** "Employee" includes a "leased worker," a "volunteer worker" and a "temporary worker."
- BB.** "Executive officer" means:
- 1. A person holding any of the officer positions created by the "Insured Entity's" charter, constitution, by-laws or any other similar governing document;
 - 2. A corporate risk manager;
 - 3. The "Insured Entity's" in-house general counsel; and
 - 4. Any "employee" who is responsible for the "Insured Entity's" property and casualty insurance or claim reporting.
- CC.** "First Named Insured" means the entity first listed as a "Named Insured" in the Declarations.
- DD.** "Force majeure" means the following unforeseen events if and to the extent they prevent the "Insured Entity" from completing "insured product" or "insured work":
- 1. Acts of governmental authorities;
 - 2. Earthquake;
 - 3. Epidemic;
 - 4. Epizootic;
 - 5. Fire;
 - 6. Flood;
 - 7. Military operations;
 - 8. Other natural or man-caused disasters; or
 - 9. War, riot or civil commotion.
- EE.** "Hazardous properties" includes radioactive, toxic or explosive properties.
- FF.** "Impaired property" means tangible property, other than "insured product" or "insured work," that cannot be used or is less useful because:
- 1. It incorporates "insured product" or "insured work" that is known or thought to be defective, deficient, inadequate or dangerous; or
 - 2. The "insured" has failed to fulfill the terms of a contract or agreement;
- if such property can be restored to use by:
- a. The repair, replacement, adjustment or removal of "insured product" or "insured work"; or
 - b. The "insured" fulfilling of the terms of the contract or agreement.
- GG.** "Incident" means a "data breach," an "occurrence," an offense or "wrongful act."
- HH.** "Institutional Review Board" means a board, committee, panel or similar group designated, directed or requested by a person or organization to oversee, review or approve "clinical trials."

II. “Insured” means the “Insured Entity” and:

- 1.** Any individual who was, is or becomes the “Insured Entity’s” officer, director, member or manager (of a limited liability company), or partner including joint venture partner, but only with respect to their duties as officers, directors, members, managers or partners of the “Insured Entity’s” business;
- 2.** The “Insured Entity” stockholders, but only with respect to their liability as stockholders; and
- 3.** The “Insured Entity” “employees,” but only for acts within the scope of their employment or while performing duties related to the conduct of the “Insured Entity’s” business. Voluntary participation as a human test subject in a “clinical trial” will not considered to be within the scope of employment or performance of duties.

No “employee” is an “insured” for:

a. “Bodily injury” or “personal and advertising injury”:

- (1)** To the “Insured Entity,” or to its directors, officers, members or managers, partners, or to a co-employee while such injured person is either in the course of his or her employment or performing duties related to the conduct of the “Insured Entity’s” business;
- (2)** To the spouse, “domestic partner,” child, parent, brother or sister of a co-employee as a consequence of subparagraph **a.(1)** above; or
- (3)** For which there is any obligation to share “damages” and “defense costs” with or repay someone else who must pay “damages” and “defense costs” because of the injury described in subparagraphs **a.(1)** or **a.(2)** above.

b. “Property damage” to property:

- (1)** Owned, occupied or used; or
- (2)** Rented to, in the care, custody or control of, or over which physical control is being exercised for any purpose by;

the “Insured Entity,” any of its “employees,” any partner or member (if the “Insured Entity” is a partnership or joint venture), or any member (if the “Insured Entity” is a limited liability company).

- 4.** Any person (other than the “Insured Entity’s” “employee”), or any organization while acting as the “Insured Entity’s” real estate or property manager.
- 5.** “Contract research organizations,” medical or biotechnology advisors, “clinical trial consultants,” “institutional review boards,” “life science product sales consultants” and “clinical trial investigators” (other than the “Insured Entity” or its “employees”), but only with respect to their work performed for or on behalf of the “Insured Entity.”

No such person or organization is an “insured” with respect to:

- a.** Any representation or warranty unauthorized by the “Insured Entity”;
- b.** Any physical or chemical change in “insured product” made intentionally by such person without the “Insured Entity’s” consent; or
- c.** Such person or organization’s rendering or failing to render “professional services” or advice, unless:
 - (1)** The injury or “damages” arise directly out of the use of “insured products” or “insured work”;
 - (2)** The “professional service” or advice is within the scope of a “clinical trial” and is in accordance with written protocol of the “clinical trial”; and

- (3) The injury or “damages” arise out of the assumption of liability in a contract or agreement;
or
 - d. Reckless or willful violation of any law, order, ordinance, regulation or statute.
6. Persons (other than the “Insured Entity’s” “employees”) or organizations acting for the “Insured Entity”; but only:
- a. With respect to their liability for “damages” and “defense costs” resulting from activities within the scope of a “insured contract” to which this policy applies;
 - b. To the extent such contract or agreement requires the person or organization to be afforded status as an “insured”; and
 - c. For such activities that occurred after the execution of the contract or agreement.
7. Persons or organizations who are vendors of “insured products,” but only with respect to their liability for “damages” and “defense costs” resulting from the distribution or sale of “insured product” in the regular course of their business.

No such person or organization is an “insured” with respect to:

- a. Assumption of liability (of another person or organization) by them in a contract or agreement. This limitation does not apply to the liability for “damages” and “defense costs” to which this insurance applies, that such person or organization would have in absence of such contract or agreement;
- b. Any representation or warranty that is not authorized by the “Insured Entity”;
- c. Any physical or chemical change in “insured product” made intentionally by the vendor;
- d. Repackaging, unless unpacked solely for the purpose of inspection, demonstration, testing or the substitution of parts under instruction from the manufacturer and then repacked in the original container;
- e. Failure to make 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 “insured product”;
- f. Demonstration, installation, servicing or repair operations, except such operations performed at the vendor’s premises in connection with the sale of “insured product”;
- g. The vendor’s rendering or failing to render “professional services”; or
- h. Reckless or willful violation of any law, order, ordinance, regulation or statute.

Further, none of the following are an insured:

- (1) Any person or organization from whom the “Insured Entity” has acquired “insured products,” or any container, ingredient or part entering into, accompanying or containing “insured products.”
 - (2) Any person or organization that recklessly or willfully violated or consented to any violation of law, regulation or order as described in **SECTION I—PRODUCTS-WORK HAZARD LIABILITY COVERAGE**, subsection **B. PRODUCTS-WORK HAZARD EXCLUSIONS**, paragraph **21. Unapproved Off-Label Promotion**.
8. Any other person or organization to whom or to which the “Insured Entity” is obligated by virtue of a written contract, agreement or permit to provide such insurance as afforded by this policy, but only with respect to liability arising out “insured product,” “insured work” or “professional service” performed by the “Insured Entity” or on its behalf for that “insured.”

This provision does not apply:

- a. Unless the written contract or agreement has been executed, or the permit has been issued, prior to the “bodily injury,” “property damage,” “personal and advertising injury,” “professional services injury” or any other injury; or
- b. To any person or organization:
 - (1) For “bodily injury,” “property damage,” “personal and advertising injury,” “professional services injury” or any other injury arising out of that other person’s or organization’s sole negligence; or
 - (2) Included as an “insured” by an endorsement issued by us and made a part of this policy.

The estates, heirs, legal representatives, assigns, spouses and any “domestic partner” of natural person “insureds” shall be considered “insureds” under this policy; provided, however, coverage is afforded to such estates, heirs, legal representatives, assigns and spouses only for a “claim” or “suit” arising solely out of their status as such and, in the case of a spouse or “domestic partner,” where such “claim” or “suit” seeks “damages” from marital community property, jointly held property or property transferred from the “insured” to the spouse or “domestic partner.”

JJ. “Insured contract” means a written contract or agreement pertaining to the “Insured Entity’s” business under which the “insured” assumes the tort liability of another party to a third person or organization, provided such contract or agreement is executed prior to an “occurrence,” offense or “wrongful act.” Tort liability means a liability that would be imposed by law in the absence of any contract or agreement.

KK. “Insured Entity” means any “Named Insured” and any subsidiary or any newly acquired subsidiary.

LL. “Insured product”

1. Means:

- a. Any goods or products, other than real property:
 - (1) Created, designed, developed, manufactured, researched or tested;
 - (2) Sold, leased, licensed, rented, handled, marketed, distributed to others; or
 - (3) Disposed of;by the “Insured Entity” or others on the “Insured Entity’s” behalf; and
- b. Containers (other than vehicles), materials, parts or equipment furnished in connection with such goods or products;

2. Includes:

- a. Warranties or representations made at any time with respect to the fitness, quality, durability, performance, use, handling, operation, safety or maintenance of “insured product”; and
- b. The providing of or failure to provide warnings or instructions.

MM. “Insured work”

1. Means:

- a. Work performed by the “Insured Entity” or on its behalf solely in connection with “insured product” or its “clinical trials,” including, but not limited to testing, review, installation, maintenance, or repair of “insured product”; and
- b. Materials, parts or equipment furnished in connection with such work.

2. Includes:
 - a. Warranties or representations made at any time with respect to the fitness, quality, durability, performance, use, handling, operation, safety or maintenance of “insured work”; and
 - b. The providing of or failure to provide warnings or instructions.

NN. “Leased worker” means a person leased to the “insured” by a labor leasing firm under an agreement between the “insured” and the labor leasing firm, to perform duties related to the conduct of the “insured’s” business. “Leased worker” does not include a “temporary worker.”

OO. “Life science product” means a “pharmaceutical drug,” “biological product,” “medical device,” or “nutraceutical,” including their active ingredients.

PP. “Life science product sales consultants” means a person or organization engaged to provide service, advice or instruction in connection with the dispensing, distribution, furnishing or sale of a “life science product,” other than in connection with a “clinical trial.”

QQ. “Loading or unloading” means the handling of property:

1. After it is moved from the place where it is accepted for movement into or onto an aircraft, watercraft or “auto”;
 2. While it is in or on an aircraft, watercraft or “auto”; or
 3. While it is being moved from an aircraft, watercraft or “auto” to the place where it is finally delivered;
- but “loading or unloading” does not include the movement of property by means of a mechanical device, other than a hand truck, that is not attached to the aircraft, watercraft or “auto.”

RR. “Medical Device” means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is:

1. Recognized by the United States Food and Drug Administration, any supplement to them, or their foreign equivalent;
2. Intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals; or
3. Intended to affect the structure or any function of the body; and

which does not achieve its primary intended purposes through chemical action within or on the body of man or animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

SS. “Medical expenses” means reasonable expense for necessary:

1. First aid administered at the time of an “occurrence”;
2. Ambulance or hospital services;
3. Surgical, medical, imaging, dental, or optometric services;
4. Medical equipment and supplies, including prosthetic devices;
5. Professional nursing or rehabilitation services; or
6. Funeral services.

TT. “Medical services” means dental, medical, psychological, psychiatric, nursing, surgical, x-ray or other similar service performed by a medical intern, resident, technician, nurse, physician or other medical professional, and the related dispensing or furnishing of food, beverages, medications or appliances or any “life science product” in connection with such services, and the postmortem handling of remains including autopsies, donation or other procedures.

UU. “Mobile equipment” means any of the following types of land vehicles, including any attached machinery or equipment:

1. Bulldozers, farm machinery, forklifts and other vehicles designed for use principally off public roads;
2. Vehicles maintained for use solely on premises owned by or rented to you;
3. Vehicles that travel on crawler treads;
4. Vehicles, whether self-propelled or not, maintained primarily to provide mobility to permanently mounted:
 - a. Power cranes, shovels, loaders, diggers or drills; or
 - b. Road construction or resurfacing equipment such as graders, scrapers or rollers;
5. Vehicles not described in paragraphs 1., 2., 3. or 4. above that are not self-propelled and are maintained primarily to provide mobility to permanently attached equipment of the following types:
 - a. Air compressors, pumps and generators, including spraying, welding, building cleaning, geophysical exploration, lighting and well servicing equipment; or
 - b. Cherry pickers and similar devices used to raise or lower workers; and
6. Vehicles not described in paragraphs 1., 2., 3. or 4. above maintained primarily for purposes other than the transportation of persons or cargo.

However, self-propelled vehicles with the following types of permanently attached equipment are not “mobile equipment,” but will be considered “autos”:

1. Equipment designed primarily for:
 - a. Snow removal;
 - b. Road maintenance, but not construction or resurfacing; or
 - c. Street cleaning;
2. Cherry pickers and similar devices mounted on automobile or truck chassis and used to raise or lower workers; and
3. Air compressors, pumps and generators, including spraying, welding, building cleaning, geophysical exploration, lighting and well servicing equipment.

VV. “Named Insured” means the entity or entities shown in the Declarations.

WW. “Nuclear facility” means:

1. Any “nuclear reactor”;
2. Any equipment or device designed or used for:
 - a. Separating the isotopes of uranium or plutonium;
 - b. Processing or utilizing “spent fuel”; or
 - c. Handling, processing or packaging “waste”;
3. Any equipment or device used for the processing, fabricating or alloying of “special nuclear material” if at 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.

- XX.** “Nuclear material” means “source material,” “special nuclear material” or “by-product material.”
- YY.** “Nuclear reactor” means an apparatus designed or used to sustain nuclear fission in a self-supporting chain reaction or to contain a critical mass of fissionable material.
- ZZ.** “Nutraceutical” means any product intended to supplement the diet as defined by the United States Food and Drug Act, the United States Dietary Supplement Health and Education Act, or its foreign equivalent, whether intended for ingestion or topical application. However, “nutraceutical” does not include any “pharmaceutical drug,” “biological product,” “medical device,” food or beverage.
- AAA.** “Occurrence” means an accident, including continuous or repeated exposure to substantially the same general harmful conditions.
- BBB.** “Personal and advertising injury” means injury, including consequential “bodily injury,” arising out of one or more of the following offenses:
1. False arrest, detention or imprisonment;
 2. Malicious prosecution or abuse of process;
 3. The 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;
 4. Oral or written publication, in any manner, of material that slanders or libels a person or organization or disparages a person’s or organization’s goods, products or services;
 5. Oral or written publication, in any manner, of material that violates a person’s right of privacy;
 6. The use of another’s advertising idea in the “Insured Entity’s” “advertisement”; or
 7. Infringing upon another’s copyright, trade dress or slogan in the “Insured Entity’s” “advertisement.”
- CCC.** “Pharmaceutical drug” means a synthetic or natural chemical:
1. Recognized by any official pharmacopoeia or formulary and any of their supplements or the equivalent of such documents in any foreign jurisdiction;
 2. Intended for use in the diagnosis, cure, mitigation, treatment or prevention of injury, sickness or disease;
 3. Which affects the structure or any function of a human or animal body; or
 4. Used as a component of any product described in paragraph **1.** or **2.** above.
- However, “pharmaceutical drug” does not include any “biological product,” “medical device,” “nutraceutical,” food or beverage.
- DDD.** “Pollutants” means any solid, liquid, gaseous or thermal irritant or contaminant, including smoke, vapor, soot, fumes, acids, alkalis, chemicals and waste. Waste includes materials to be recycled, reconditioned or reclaimed.
- EEE.** “Products-work hazard” means:
- All “bodily injury,” “property damage” and “personal and advertising injury” occurring away from premises the “insured” owns or rents and arising out of “insured product” or “insured work” except:
1. Products that are still in the “insured’s” physical possession; or

2. Work that has not yet been completed or abandoned. However, “insured work” will be deemed completed at the earliest of the following times:
 - a. When all of the work called for in the “insured’s” contract has been completed.
 - b. When all of the work to be done at a premise has been completed if the “insured’s” contract calls for work at more than one premises.
 - c. When that part of the work done at a premise has been put to its intended use by any person or organization other than another contractor or subcontractor working on the same project.

Work that may need service, maintenance, correction, repair or replacement, but which is otherwise complete, will be treated as completed.

However, “products-work hazard” does not include “bodily injury” or “property damage” arising out of:

1. 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 “insured” and that condition was created by the “loading or unloading” of that vehicle by any “insured”; or
2. The existence of tools, uninstalled equipment, or abandoned or unused materials.

FFF. “Professional liability claim” means a “claim” or “suit” seeking monetary damages for an actual or alleged “wrongful act” in the rendering of, or the failure to render, “professional services,” but solely to the extent such “claim” or “suit” alleges injury other than “bodily injury,” “property damage” or “personal and advertising injury.”

GGG. “Professional services” means those services performed by the “insured,” for a fee or other remuneration, but only for services that are specified in an “insured contract” that was executed:

1. Prior to the date of the “wrongful act” giving rise to the “claim” or “suit”; and
2. After the Retroactive Dates, if any, shown in the Declarations.

However, “professional services” does not include “medical services.”

HHH. “Professional services injury” means financial loss sustained by an individual or organization caused by or resulting from the rendering of or failure to render “professional services.”

III. “Property damage” means:

1. Physical injury to tangible property, including the resulting loss of use of that property. All such loss of use shall be deemed to occur at the time of the physical injury that caused it; or
2. Loss of use of tangible property that has not been physically injured. All such loss of use shall be deemed to occur at the time of the “occurrence” that caused it.

For the purposes of this insurance, electronic data is not tangible property.

As used in this definition, electronic data means facts, concepts and information converted to a form useable for communications, interpretation or processing by electronic and electromechanical data processing or electronically controlled equipment and includes programs, software and other coded instructions for the processing and manipulation of data or the direction and manipulation of such equipment.

JJJ. “Protected person” means a person whose nonpublic personal information is protected from unauthorized disclosure or access by a privacy law. However, this does not include an “employee,” “leased worker” or “temporary worker” of any “insured” unless the “employee,” “leased worker” or “temporary worker” is participating in a “clinical trial” and the information was collected for the purpose of the person’s participation in the “clinical trial.”

- KKK.** “Protected personal information” means the first and last name of a “protected person” in combination with any one or more of the following:
1. Social security number;
 2. Medical or healthcare information or data, or other protected health information;
 3. Driver’s license number or state identification number;
 4. Account number, credit card number or debit card number in combination with any required security code;
 5. Access code or password that would permit access to that person’s financial account; or
 6. Other nonpublic personal information as defined in an applicable privacy law.
- LLL.** “Related claims” means all “claims” or “suits” that have as a common nexus any fact, situation, event, transaction, cause or series of facts, situations, events, transactions or causes.
- MMM.** “Related data breaches” means all “data breaches” giving rise to “data breach economic injury” that have as a common nexus any fact, situation, event, transaction, cause or series of facts, situations, events, transactions or causes.
- NNN.** “Related occurrences” means all “occurrences” giving rise to “bodily injury” or “property damage” that have as a common nexus any fact, situation, event, transaction, cause or series of facts, circumstances, situations, events, transactions or causes.
- OOO.** “Related offenses” means all offenses giving rise to “personal and advertising injury” that have as a common nexus any fact, situation, event, transaction, cause or series of facts, situations, events, transactions or causes.
- PPP.** “Related wrongful acts” mean all acts or omissions in the rendering of or failure to render “professional services” that have as a common nexus any fact, situation, event, transaction, cause or series of facts, situations, events, transactions or causes.
- QQQ.** “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.
- RRR.** “Spent fuel” means any fuel element or fuel component, solid or liquid, which has been used or exposed to radiation in a “nuclear reactor.”
- SSS.** “Suit” means a civil proceeding commenced by the service of a complaint or similar pleading in which “damages” because of “bodily injury,” “property damage,” “personal and advertising injury,” “professional services injury” or “data breach economic injury” to which this insurance applies are alleged. “Suit” includes:
1. An arbitration proceeding in which such “damages” are claimed and to which the “insured” must submit or does submit with our consent; or
 2. Any other alternative dispute resolution proceeding in which such “damages” are claimed and to which the “insured” submits with our consent.
- TTT.** “Temporary worker” means a person who is furnished to the “insured” to substitute for a permanent “employee” on leave or to meet seasonal or short-term workload conditions.
- UUU.** “Volunteer worker” means a person who is not the “insured’s” “employee,” and who donates his or her work and acts at the direction of and within the scope of duties determined by you, and is not paid a fee, salary or other compensation by the “insured” or anyone else for their work performed for you.

WV. “Waste” means any waste material:

1. Containing “by-product material” other than the tailings or wastes produced by the extraction or concentration of uranium or thorium from any ore processed primarily for its “source material” content; and
2. Resulting from the operation by any person or organization of any “nuclear facility” included under the first two paragraphs of the definition of “nuclear facility.”

WWW. “Wrongful act” means any actual or alleged negligent act, error or omission in the rendering of “professional services” by any “insured” on the “Insured Entity’s” behalf.