HANOVERfUSION

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Supplemental Application

UNDERWRITTEN BY: THE HANOVER INSURANCE COMPANY

CLAIMS MADE NOTICE

THIS POLICY PROVIDES COVERAGE ON A CLAIMS-MADE BASIS. SUBJECT TO ITS TERMS, THIS POLICY APPLIES ONLY TO "CLAIMS" FIRST MADE AGAINST "YOU" DURING THE "POLICY PERIOD", AUTOMATIC EXTENDED REPORTING PERIOD OR ANY PURCHASED OPTIONAL EXTENDED REPORTING PERIOD THAT MAY APPLY. PLEASE READ THE POLICY CAREFULLY TO DETERMINE RIGHTS, DUTIES, COVERAGE AND COVERAGE RESTRICTIONS.

"CLAIM EXPENSE" WITHIN LIMITS

THIS CLAIMS-MADE POLICY PROVIDES FOR "CLAIM EXPENSE" PAYABLE WITHIN, AND NOT IN ADDITION TO, THE LIMITS OF INSURANCE. "CLAIM EXPENSE" WILL REDUCE AND MAY EXHAUST THE LIMIT OF INSURANCE, AND WILL BE APPLIED AGAINST THE DEDUCTIBLE. PLEASE READ THE POLICY CAREFULLY TO DETERMINE RIGHTS, DUTIES, COVERAGE AND COVERAGE RESTRICTIONS.

APPLICATION INSTRUCTIONS

Please answer all required sections of questions completely. The following sections are required for all applicants: General Information, Products-Completed Operations Liability, and Products-Completed Operations—Regulatory and Risk Management. To the left, you are able to select the additional coverage options you would like to apply for to access the required questions for each coverage.

Whenever used in this Application, the term you or your(s) or the Applicant shall mean the Named Insured and all subsidiaries, unless otherwise stated.

GENERAL INFORMATION

Your Business Operations

1. Name of Applicant: _____
2. Address of Applicant: _____
3. Website Address: _____
4. Years in Business: _____
5. Have you ever operated under another name? ☐ Yes ☐ No
   If Yes, please explain: _____
6. Do you have a parent company? ☐ Yes ☐ No
   If Yes, provide name: _____
7. Please list all your subsidiaries and your percentage of ownership in each:
   _____
8. In the past 5 years, have you engaged in any mergers, acquisitions, or divestitures? ☐ Yes ☐ No
   If Yes, please provide the date and whether you acquired, retained or divested assets, liabilities or both for each transaction. _____
9. For each merger or acquisition, did your due diligence process include the following:
   a. Review of prior and pending litigation? ☐ Yes ☐ No
      If Yes, please provide a brief description: _____
   b. Evaluation of all outstanding contracts or service agreements to be included as part of the transaction? ☐ Yes ☐ No
   c. Analysis of intellectual property rights, including any third-party interest in or liens on these rights? ☐ Yes ☐ No

Client Insurance Information

Please provide information on your current insurance program:

POLICY PERIOD	INSURANCE COMPANY	COVERAGE	LIMITS	DEDUCTIBLE	RETROACTIVE DATE	PREMIUM
			$	$		$
			$	$		$
			$	$		$
			$	$		$

1. Is your current Products-Completed Operations Liability coverage form provided on a Claims-Made basis? ☐ Yes ☐ No
2. Have you discontinued or ceased to provide any products, services or operations in the last five years? ☐ Yes ☐ No
   a. If Yes, please provide details: _____
   b. And if Yes, do you provide continuing services, support or other remedies for discontinued products, services or operations? ☐ Yes ☐ No
      If Yes, please provide details: _____
3. Does your current insurance program exclude any of your clinical trials, products or services? ☐ Yes ☐ No
   If Yes, please provide details: _____

Requested Insurance Program

Please provide information on your requested insurance program:

COVERAGE	LIMITS	DEDUCTIBLE	RETROACTIVE DATE(S)
Products-Completed Operations Liability	$	$	
Errors & Omissions	$	$	
Information Security	$	$	
Privacy and Personal Injury	$	$	
Media and Content	$	$	
Data Breach Expense	$	$	Non-Applicable
Products Recall Expense	$	$	Non-Applicable
Human Clinical Trial Expense	$	Non-Applicable	Non-Applicable

1. Please provide a description of your business operations:

   _____

   _____

2. Describe any new products or services, entering the market that are substantially different in scope or end use than your current products or services?

   _____

   _____

3. Do you anticipate any significant changes in the nature of your business over the next 12 months? ☐ Yes ☐ No
   If Yes, please provide details: _____

4. Please provide a breakdown of your revenue:

SOURCES OF REVENUE	CURRENT ANNUAL REVENUES	PROJECTED ANNUAL REVENUES
Total U.S. Revenue	$	$
Total Foreign Revenue	$	$
Total Revenue	$	$

5. Please provide a breakdown of your products or services by percentage of your total revenue:

SOURCES OF REVENUE	PERCENTAGE OF YOUR TOTAL REVENUE
Pharmaceuticals	%
Medical Devices	%
Digital Health	%
Contract Research Organization and/or Research Institute	%
Other:	%

6. Do you have any association, past or present, with banned products? ☐ Yes ☐ No

   If Yes, please provide details: _____

7. Have any of your products, services or operations been subject to an investigation by any U.S. or foreign government agency? ☐ Yes ☐ No

   If Yes, please provide details: _____

8. Do you utilize nanotechnology in the development, delivery or manufacturing of your products? ☐ Yes ☐ No

   If Yes, please provide details: _____

9. Are your products and services HIPAA compliant? ☐ Yes ☐ No

   If No, please provide details: _____

10. Please check the box if you have studies or products (past, present or planned) involving any of the following classes of products:

☐ Addictive Substance	☐ Known Carcinogen	☐ Radiation-Emitting Technologies
☐ Birth Control or Fertility	☐ Known Mutagen	☐ SSRIs or SNRIs
☐ Gene Therapy Known	☐ Teratogen	☐ Steroids
☐ Hormone Replacement Products	☐ Mercury	☐ Vaccines
☐ HPAPIs or HPAIs	☐ Pediatric/Minors/Pregnant Women	☐ Weight Management

History

1. In the past 5 years:

   a. Have you received any claims or suits (insured or not) claiming damages associated with your products, services or human clinical trials? ☐ Yes ☐ No

      If Yes, provide details at the end of section.

   b. Have you given notice of any claim, circumstance or potential claim to any insurer under any insurance coverage referred to above? ☐ Yes ☐ No

      If Yes, provide details at the end of section.

   c. Are you aware of any facts or circumstances associated with your products or services that could reasonably be expected to result in a claim or suit? ☐ Yes ☐ No

      If Yes, provide details at the end of section.

2. Within the past 3 years:
   a. Have you had contract disputes alleging non-performance of your products or services? ☐ Yes ☐ No
      If Yes, provide details at the end of section.
   b. Have your customers withheld payment due to a contract dispute? ☐ Yes ☐ No
      If Yes, provide details at the end of section.
   c. Have you sued any of your customers for non-payment? ☐ Yes ☐ No
      If Yes, provide details at the end of section.
   d. Have you discovered or been accused of any type of privacy violation? ☐ Yes ☐ No
      If Yes, provide details at the end of section.
3. Within the past 3 years, have you had any policy canceled or non-renewed? ☐ Yes ☐ No
   If Yes, please provide details: _____

If you answered Yes to any of the History questions, please explain each Yes answer in detail below and provide relevant documentation:

_____

_____

_____

_____

PRODUCTS—COMPLETED OPERATIONS LIABILITY

A. Pharmaceuticals

(Please complete this section if you manufacturer or distribute a pharmaceutical. If you do not, please skip this section.)

1. Please provide a breakdown of your product revenue by product type and number of units sold:

ROUTE OF ADMINISTRATION	PRESCRIPTION	GENERIC	OVER-THE-COUNTER	PERCENTAGE OF REVENUE SOLD	NUMBER OF UNITS SOLD
Topical	☐	☐	☐	%	
Oral	☐	☐	☐	%	
Inhalable	☐	☐	☐	%	
Injectable	☐	☐	☐	%	
Transdermal	☐	☐	☐	%	
Drug Delivery	☐	☐	☐	%	
Other	☐	☐	☐	%	

2. Please provide an overview of your products and their intended usages.

   _____

3. Do you manufacture a biologic therapeutic? ☐ Yes ☐ No
   If Yes, please provide details. _____
4. Do you manufacture an Active Pharmaceutical Ingredient (API) for: ☐ Yourself ☐ Others
   If Yes, please provide details. _____
5. Do you have any past, present or planned products that do not have formal FDA approval for marketing? ☐ Yes ☐ No
   If Yes, please provide details. _____
6. Please check the box where you have studies, products, or services (past, present or future) involving any of the following specific pharmaceutical products:

☐ Accutane
☐ Bisphosphonate
☐ Cisapride
☐ Dexfenthuramine
☐ Diethylstilbestrol (DES)
☐ Ephedra
☐ Ephedrine
☐ Flenfluramine
☐ Isotretinoin
☐ L-Tryptophan
☐ Metoclopramide
☐ Opioids
☐ Phentermine
☐ Phenylpropanolamine
☐ Pseudoephedrine
☐ Redux
☐ Rosiglitazone
☐ Thalidomide
☐ Thimerosal
☐ Troglitazone
☐ Phospho soda, sodium phosphate, or any phosphor soda or sodium phosphate based agents

7. Do you manufacturer or distribute cosmeceuticals, nutraceuticals, vitamins or food supplements for yourself or others? ☐ Yes ☐ No

If Yes, please answer the remaining questions in this section:

a. Please describe the nature of your products. _____

b. Do any of your products make health or lifestyle claims/benefits? ☐ Yes ☐ No

If Yes, please provide details. _____

c. Have any of your products ever fit the definition of a new dietary ingredient? ☐ Yes ☐ No

If Yes, have pre-market safety reviews been conducted per regulations? ☐ Yes ☐ No

d. Have any of your products ever had an active ingredient that would be defined as a drug by a regulatory agency? ☐ Yes ☐ No

If Yes, please provide details. _____

e. Do you sell any muscle building, weight management or sexual enhancement products? ☐ Yes ☐ No

f. Do you sell any of your products through a multi-level marketing system? ☐ Yes ☐ No

B. Medical Device

(Please complete this section if you manufacture, assemble, distribute or provide service to components and/or finished goods related to medical devices, biotechnology products or laboratory products/technologies. If you do not, please skip this section.)

1. How would you define yourself? Please check the box(s) below which apply to.

☐ Medical Device ☐ Medical Device Consumables ☐ Laboratory Analytical Equipment and Technologies

☐ Biotechnology Products or Consumables (excludes anything administered into the body)

2. Please provide a breakdown of your revenue by revenue source:

SOURCE OF REVENUE	FOR YOURSELF	FOR OTHERS	PERCENTAGE OF TOTAL REVENUE
Component manufacturer of a product	☐	☐	%
Contract manufacturer of a product	☐	☐	%
Manufacturer of a product	☐	☐	%
Distributor of a product	☐	☐	%
Installer, servicer or repairer of a product	☐	☐	%
Refurbisher of a product	☐	☐	%
Other:	☐	☐	%

3. Please provide an overview of your products and their intended usages.

_____

4. Are your products labeled research use only? ☐ Yes ☐ No

5. If you are a component or a contract manufacturer:

a. Describe the Finished Good product. _____

b. Do you provide design, engineering and prototype services? ☐ Yes ☐ No

If Yes, please provide details. _____

c. What percentage of your work is completed to customer specifications? _____%

d. Do you have a formal process for approval and acceptance by your customer for any specification, material, or manufacturing process modifications? ☐ Yes ☐ No

If Yes, please provide details. _____

e. Are you aware of any product recalls by your customers that resulted from your product or work? ☐ Yes ☐ No

If Yes, please provide details. _____

6. Please check the box where you have any past, present or planned involvement associated with any of the following:

☐ Aerospace or aircraft
☐ Automotive
☐ Biologics
☐ Defense or military
☐ Drug delivery system
☐ Implantable medical device
☐ Industrial automation
☐ Latex
☐ Life sustaining or life supporting medical device
☐ Physical security devices

If you checked any of the boxes above, please provide an explanation describing your product or work below:

_____

_____

_____

C. Digital Health

(Please complete this section if you provide digital health products. If you do not, please skip this section.)

1. Please check all the activities below that apply to your company and the end-use environment(s) for your products.

PRODUCTS	PRODUCT END-USE ENVIRONMENT(S)				
	CLINICAL	PHARMACY	LABORATORY	HOME	MOBILE
Electronic Health, Electronic Medical or Personal Health Record	☐	☐	☐	☐	☐
E-Prescriptions	☐	☐	☐	☐	☐
Clinical Decision Support	☐	☐	☐	☐	☐
Computerized Physician Ordering Entry	☐	☐	☐	☐	☐
Drug-to-Drug Interactions	☐	☐	☐	☐	☐
Health Kiosks	☐	☐	☐	☐	☐
HIPAA Compliance Software/Advisory/Services	☐	☐	☐	☐	☐
Medication Coding or Dispensing	☐	☐	☐	☐	☐
Medical, Health or Nutritional Content/Advisory/Services	☐	☐	☐	☐	☐
Patient Archiving Capturing System	☐	☐	☐	☐	☐
Patient or Clinical Communication Portal	☐	☐	☐	☐	☐
Patient Management Software	☐	☐	☐	☐	☐
Remote Medical Education for Clinicians	☐	☐	☐	☐	☐
Remote Patient Monitoring	☐	☐	☐	☐	☐
Unregulated FDA Mobile Applications	☐	☐	☐	☐	☐
Other:	☐	☐	☐	☐	☐

2. Do you provide standard or customizable product solutions? ☐ Yes ☐ No

   If Yes, please provide details. _____

3. Do you perform any functions, activities or provide any product or service that involves the use or disclosure of protected health information? ☐ Yes ☐ No

   If Yes, please provide details. _____

4. Do you provide any hosting, archiving or cloud services of your customers' data? ☐ Yes ☐ No

   If Yes, please provide details. _____

5. How do your products interface with other digital health products or medical devices?

   _____

6. If you develop or publish Electronic Health Records or Electronic Medical Records software, is your software certified by the Office of the National Coordinator for Health Information Technology? ☐ Yes ☐ No

7. Do you manufacture or distribute any medical devices (components and/or finished goods) to complement your product solution(s) identified above? ☐ Yes ☐ No

   If Yes, please provide details. _____

8. Are any of your products (past, present or planned) considered an FDA regulated medical device? ☐ Yes ☐ No

   If Yes, please complete section B– Medical Device of this Application.

D. Contract Research

(Please complete this section if you operate as a clinical or contract research organization and/or a research institute. If you do not, please skip this section.)

1. How would you define yourself? Please check the box(s) below which apply.

   ☐ Pre-Clinical Contract Research Organization

   ☐ Clinical Research Organization

   ☐ Research Institute

2. Please check all the activities below that apply to your company:

PRE-CLINICAL	FOR YOURSELF	FOR OTHERS	CLINICAL	FOR YOURSELF	FOR OTHERS
Bench research	☐	☐	Protocol and/or consent form development	☐	☐
Medicinal chemistry including target discovery and validation	☐	☐	Clinical trial management and/or data collection	☐	☐
Lead optimization and validation	☐	☐	Regulatory support and/or statistical analysis	☐	☐
In-vitro screening	☐	☐	Pharmacovigilance	☐	☐
Animal studies	☐	☐	Medical or pathology services performed onsite	☐	☐
Toxicology and/or pathology	☐	☐	Licensing of technology, intellectual property or data to others		☐
Other:	☐	☐	Providing clinical instructions to others		☐
Other:	☐	☐	Other:	☐	☐

3. Do you act as a sponsor or investigator for any clinical trials? ☐ Yes ☐ No

   If Yes, please explain _____

4. Do you support the development and / or commercialization of any products? ☐ Yes ☐ No

   If Yes, please explain _____

5. Do you receive royalties for patents or other intellectual property? ☐ Yes ☐ No

   If Yes, please explain _____

6. Is someone within your organization responsible for intellectual property management and transfer of technology to others, inter-institutional agreements, etc.? ☐ Yes ☐ No

   If Yes, please identify the individual by title _____

7. Do you have protocols for identifying and handling suspected research fraud? ☐ Yes ☐ No

8. If you are a research institute only:

   a. How are you funded? _____

   b. What are your areas of research? _____

E. Clinical Trials

(Please complete this section if you are or plan to conduct a clinical trial. If you do not, please skip this section.)

1. Please list your clinical trials, present and planned, for the next 12 months:

PRODUCT NAME & PROTOCOL NUMBER	# OF NEW SUBJECTS TO BE ENROLLED OVER THE NEXT POLICY PERIOD	INDICATION	CLINICAL TRIAL PHASE (I, II, III OR IV)	COUNTRIES WHERE THE TRIAL TAKES PLACE

Please attach an IRB approval, clinical trial protocol and informed consent document for all clinical trials scheduled to occur over the next 12 months.

2. How many clinical trials have you sponsored in the past 3 years? _____
3. What is the total number of human subjects enrolled in the last 3 years? _____
4. What is the number of expanded access or compassionate use subject participants anticipated over the next 12 months? _____
5. Have any of your clinical trials been classified as significant risk by the FDA or IRB? ☐ Yes ☐ No
   If Yes, please provide details. _____
6. Have any of your clinical trials been suspended or discontinued in whole, or in part, because of safety reasons? ☐ Yes ☐ No
   If Yes, please provide details. _____
7. What is the number of clinical trial "For Cause Audits" conducted by you or a regulatory agency in the past 5 years? _____
   Please provide details. _____
8. Have any clinical investigators been cited for regulatory violations? ☐ Yes ☐ No
   If Yes, please provide details. _____
9. Do you ever act as both trial sponsor and clinical investigator? ☐ Yes ☐ No
   If Yes, please provide details. _____
10. Do you ever provide material or product for investigator sponsored trials? ☐ Yes ☐ No
    If Yes, please provide details. _____
11. Do you have formalized Clinical Trial Suspension SOPs in place? ☐ Yes ☐ No

PRODUCTS—COMPLETED OPERATIONS—REGULATORY AND RISK MANAGEMENT

Regulatory

1. Are you in compliance with Title 21 CFR Part 99 – Dissemination of Information on Unapproved/New Uses for Marketed Drugs, Biologics and Devices? ☐ Yes ☐ No
   If No, provide details. _____
2. Have you had any product(s) requiring the addition of a black box or significant safety warning to an existing label or instruction manual in the past 5 years? ☐ Yes ☐ No
   If Yes, please provide details. _____

3. Do you have any outstanding FDA issues? ☐ Yes ☐ No

   If Yes, please provide details. _____

4. Have you been cited by any other regulatory agency (other than the FDA) for deficiencies and/or for noncompliance in the past 3 years? ☐ Yes ☐ No

   If Yes, please provide details and your responses? _____

Risk Management

QUALITY CONTROL ASSURANCE

1. Do you have a formal risk management or quality management program? ☐ Yes ☐ No
2. Who is responsible for overseeing the Risk Management and Quality Management program? _____
3. Do your quality control procedures include formalized, standard operating procedures for the following?

   Please check all that apply:

☐ Facility sanitation controls	☐ Written systems development methodology	☐ Prototype development guidelines	☐ Customer acceptance procedure
☐ Materials and/or goods subject to atmospheric changes	☐ In-process control-point tests	☐ Finished goods or batch testing	☐ Batch records/serial product history record keeping
☐ Vendor certification/ verification process	☐ cGMP testing	☐ Labeling and packaging	☐ Written quality control program
☐ Incoming inspection of raw materials or component parts	☐ Alpha testing	☐ Shelf life and/or calibration requirements	☐ Product recall program
☐ Non-conforming material	☐ Beta testing	☐ Safe distribution of goods	☐ 3rd Party Contract manufacturing

4. Do you audit your risk management programs and standard operating procedures? ☐ Yes ☐ No
5. Do you have any sterilized products? ☐ Yes ☐ No

   If Yes:

   a. Do you use a 3rd party sterilizer? ☐ Yes ☐ No

   b. Do you sterilize the product on your premise? ☐ Yes ☐ No

   If you responded yes to either question above, please provide details:

   _____

6. Do you utilize a 3rd party vendor to package, label, warehouse or distribute your products? ☐ Yes ☐ No

   If Yes, please provide details. _____

7. How long do you retain testing and quality control records? _____
8. Are you in compliance with all applicable cGMP, GCP, GLP and QS guidelines? ☐ Yes ☐ No
9. Do you comply with any of the following industry standards? Please check all that apply:

   ☐ ANSI ☐ FDA ☐ ISO 13485 ☐ REMS ☐ Other: _____

   ☐ CE Mark I ☐ SO 9000 ☐ ISO 14971 ☐ UL / CSA / EU ☐ Other: _____

10. Do you audit your suppliers? ☐ Yes ☐ No

SALES AND MARKETING

1. How do you sell your products and/or services? _____
2. Describe the guarantees or warranties provided with your products or services. _____
3. Do you provide service agreements for your products? ☐ Yes ☐ No

   If Yes:

   a. Do you audit your company's compliance with service agreements? ☐ Yes ☐ No

   b. Do you have a written preventative maintenance program for products under a service agreement? ☐ Yes ☐ No
4. Are any of your employees or subcontractors present during medical procedures? ☐ Yes ☐ No

   If Yes:

   a. Do you have a formal policy prohibiting physical patient contact by an employee or subcontractor? ☐ Yes ☐ No

   b. Do you provide training to your employees and subcontractors regarding appropriate communication and conduct during medical procedures? ☐ Yes ☐ No
5. Do you have a formal and documented training program for sales personnel? ☐ Yes ☐ No
6. Do you have a formal and documented training program for installation, service and repair employees? ☐ Yes ☐ No
7. Do you employ or hire by contract, acting Medical Professionals? ☐ Yes ☐ No

   If Yes, please provide details. _____
8. Are your marketing, sales, regulatory, product development and post-market surveillance employees (or subcontractors) receiving formalized and documented training in regulatory requirements and product liability? ☐ Yes ☐ No
9. Do you have legal counsel review your labels and warnings, instructions for use, and advertising materials on at least an annual basis? ☐ Yes ☐ No
10. Do you obtain written customer acceptance at pre-defined milestones or project stages? ☐ Yes ☐ No
11. Do you obtain written final acceptance or other sign-off agreements from all customers upon delivery or completion of your products or service? ☐ Yes ☐ No
12. Do you have a formalized customer complaint resolution policy and procedure? ☐ Yes ☐ No
13. Do you provide documented technical training to your customers in the use of your products or services? ☐ Yes ☐ No

    If Yes, please provide details. _____

POST-MARKET SAFETY SURVEILLANCE AND COMPLAINT HANDLING

1. How do you track and trace your products? _____

   If batch produced, what is the average size? _____
2. What, if any, is the shelf-life expectancy of your product? _____
3. Do you have a formal products recall program? ☐ Yes ☐ No

   If Yes:

   a. Do you conduct test recalls? ☐ Yes ☐ No

   b. Do any of your products become part of another company's product? ☐ Yes ☐ No

   c. Are any products repackaged by any other companies? ☐ Yes ☐ No

      If Yes, please provide details. _____
4. Do you have a post-implementation product or service evaluation or review procedure in place? ☐ Yes ☐ No

5. Do you have a formal policy for documenting and responding to customer complaints or requests for changes or repairs? ☐ Yes ☐ No

   If Yes:

   a. Who is responsible for fielding customer complaints? _____

   b. Do you have an escalation process in place to resolve customer complaints? ☐ Yes ☐ No

   c. Do you have a formal Corrective and Preventative Action Program (CAPA)? ☐ Yes ☐ No

6. Do you monitor and manage off-label use of your products? ☐ Yes ☐ No

7. Please describe any actions you would take if you became aware of off-label use of your products.

   _____

   In addition, would any of the following actions apply?

   Healthcare Professional/Dear Doctor Letter ☐ Yes ☐ No

   Additional studies ☐ Yes ☐ No

   Expanded product monitoring ☐ Yes ☐ No

8. Do you allow off-label information dissemination? ☐ Yes ☐ No

   If Yes, under what conditions? _____

CONTRACT RISK TRANSFER

1. Do you have formal policies and procedures in place to obtain risk transfer documentation? ☐ Yes ☐ No

   Please check all that apply:

CONTRACT RISK TRANSFER DOCUMENTATION	SUPPLIERS	VENDORS	CONTRACT MFG.	SUBS OR INDEPENDENT CONTRACTORS	STERILIZERS	DISTRIBUTORS	OEMs	CUSTOMERS
Certificates of insurance issued annually	☐	☐	☐	☐	☐	☐	☐	☐
Additional Insured Status on Products / Completed Operations Liability Policy	☐	☐	☐	☐	☐	☐	☐	☐
Hold Harmless language (in your favor or mutually beneficial)	☐	☐	☐	☐	☐	☐	☐	☐
Indemnification language (in your favor or mutually beneficial)	☐	☐	☐	☐	☐	☐	☐	☐
Contract	☐	☐	☐	☐	☐	☐	☐	☐
Purchase Orders / Invoice (Incl. Terms & Conditions)	☐	☐	☐	☐	☐	☐	☐	☐
Master Service Agreement	☐	☐	☐	☐	☐	☐	☐	☐
Distribution Agreement	☐	☐	☐	☐	☐	☐	☐	☐

2. Do you provide contractual hold harmless or indemnification to other entities? ☐ Yes ☐ No

   If Yes, please provide details: _____

III. ERRORS AND OMISSIONS (Please complete this section if you are applying for Errors & Omissions coverage)

Contract Information and Contract Risk Management

1. Do you require a written contract, with your customers, for your products or services? ☐ Yes ☐ No

   If No, please explain: _____

   If Yes, please provide a breakdown of your contract activities below:

TYPE OF CONTRACT	WHAT PERCENTAGE IS STANDARD/NON-DEVIATING	WHAT PERCENTAGE IS CUSTOMIZED TO MEET CUSTOMER REQUIREMENTS
☐ Formal Contract		
☐ Licensing Agreement		
☐ Purchase Order		
☐ Other:		

2. Do your standard contracts, licensing agreements or purchase orders contain the following provisions (check all that apply)?

   ☐ Statement of Work ☐ Exclusive Remedy ☐ Performance Milestones/Schedule of Deliverables
   ☐ Limitation of Liability ☐ Integration Clause ☐ Customer Maintenance Provision
   ☐ Limitation of Consequential Damages ☐ Force Majeure ☐ Hold Harmless/Indemnification Agreements
   ☐ Disclaimer of Warranties ☐ Arbitration Clause ☐ Conditions of customer acceptance of product or service

3. Have your standard contracts, licensing agreements or purchase orders undergone legal review? ☐ Yes ☐ No

   If No, please explain: _____

4. Are all deviations from your standard contracts, licensing agreements, purchase orders or customer supplied contracts reviewed by legal counsel? ☐ Yes ☐ No

   If No, please give examples of deviations that do not require legal review and sign off?

   _____

5. Who can approve any variation in your standard contracts, licensing agreements or purchase orders provisions?

   _____

6. Do you ever negotiate contracts, licensing agreements or purchase orders with customers that include a provision for liquidated damages? ☐ Yes ☐ No

   If Yes, please explain. _____

7. Do you ever negotiate standard contracts, licensing agreements or purchase orders with customers in which you accept liability for consequential damages? ☐ Yes ☐ No

   If Yes, please explain. _____

8. Do your sales and marketing personnel receive training regarding the acceptable provisions within your customer contracts, licensing agreements or purchase orders? ☐ Yes ☐ No
9. Do you require subcontractors or independent contractors to carry Errors and Omissions insurance? ☐ Yes ☐ No

   If Yes, what is the minimum policy limit required? $_____

10. Do you notify customers of known problems with your products or services? ☐ Yes ☐ No

    If Yes, please describe: _____

11. Do you offer 24-hour product and service customer support? ☐ Yes ☐ No
12. Do you have a process to evaluate the financial condition of your customers and suppliers? ☐ Yes ☐ No
13. What is your average contract size? _____

    What is your average contract duration? _____

14. Describe your three largest customer contracts, purchase orders, licensing agreements or projects:

CUSTOMER NAME	PRODUCT OR SERVICE PROVIDED	SIZE OF CONTRACT, PURCHASE ORDER, LICENSING AGREEMENT OR PROJECT	LENGTH OF CONTRACT

IV. INFORMATION SECURITY & PRIVACY AND PERSONAL INJURY

(Please complete this section if you are applying for Information Security & Privacy and Personal Injury coverage)

Organization—Physical and Cybersecurity

1. Who is responsible for overseeing the Information Security for your organization, products and services:

   _____

2. Is your organization and any of your employees certified in any recognized information-security standards? ☐ Yes ☐ No

   If Yes, please describe: _____

3. Does your company participate in any ISACs (Information Sharing and Analysis Center) or ISAOs (Information Sharing and Analysis Organization) for the purposes of sharing and disseminating cybersecurity information and intelligence pertaining to vulnerabilities and threats, as part of your post market cybersecurity surveillance protocol? ☐ Yes ☐ No

4. Which of the following facility security measures do you have in place? (Check all that apply)

   ☐ Key card access ☐ Biometric scanning ☐ Redundant connectivity/power/cooling
   ☐ Key card protocols ☐ Disaster recovery plan ☐ Facilities security manager
   ☐ 24-hour security surveillance ☐ Redundant network equipment ☐ Security guards

5. Which of the following network security measures do you have in place? (Check all that apply)

   ☐ Inventory of authorized and unauthorized devices
   ☐ Maintenance, monitoring and analysis of audit logs
   ☐ Account monitoring and control
   ☐ Application software security
   ☐ Email and web browser protections
   ☐ Controlled access based on the need to know
   ☐ Incident response and management
   ☐ Penetration tests and red team exercises
   ☐ Malware defenses
   ☐ Boundary defense
   ☐ Data protection
   ☐ Data recovery capability
   ☐ Continuous vulnerability assessment and remediation
   ☐ Limitation and control of network ports, protocols, and services
   ☐ Inventory of authorized and unauthorized software
   ☐ Security skills assessment and appropriate training to fill gaps
   ☐ Secure configurations for network devices such as firewalls, routers, and switches
   ☐ Secure configurations for hardware and software on mobile devices, laptops, workstations, and servers
   ☐ Controlled use of administrative privileges
   ☐ Wireless access control

6. Who is allowed access to systems on your network? (Check all that apply)

   ☐ Employees ☐ Customers ☐ Vendors ☐ Business Partners ☐ Other: _____

7. What are your screening procedures prior to granting access to your systems?_____

8. Do you require special training on protecting sensitive and confidential information for those who have access to your systems? ☐ Yes ☐ No

9. What procedures do you have in place to revoke access for employees, customers, vendors, business partners, and others who access your systems? _____

10. Do you employ an individual who manages the hiring and oversight of employees that have administrator privileges or that have control over who is granted access to sensitive and confidential information? ☐ Yes ☐ No

11. Do you engage in periodic scenario-based training, working through a series of attack scenarios fine-tuned to the threats and vulnerabilities faced by your organization? ☐ Yes ☐ No

12. Have you experienced or has your system or website been used in any type of security incident or attack (e.g. viruses, denial of service attacks, etc.)? ☐ Yes ☐ No

Website Activities

1. What is the use/purpose of your website? (Check all that apply)

   ☐ Informational only ☐ Transactional ☐ Offer remote connectivity

   ☐ To provide access to restricted information, applications or content

2. With respect to your website, do you conduct any of the following activities?

   a. Do you collect user information? ☐ Yes ☐ No

      If Yes, do your visitors have the option to opt-in or opt-out of allowing the collection or use of their information? ☐ Yes ☐ No

   b. Do you sell or share personal and/or confidential information gathered from customers or others? ☐ Yes ☐ No

      If Yes, do you notify and obtain the consent of customers and others prior to dissemination? ☐ Yes ☐ No

   c. Do you host your own website? ☐ Yes ☐ No

   d. Do you have a chat room or bulletin board? ☐ Yes ☐ No

      If Yes, please provide the following information:

      1) Who are the primary users of the chat room or bulletin board? _____

      2) Do you monitor the chat room or bulletin board? ☐ Yes ☐ No

      3) How quickly are offensive posts removed from your website? _____

      4) How quickly do you remove content when you are notified content is unacceptable or infringing?

      _____

3. Do you have a Privacy Policy? ☐ Yes ☐ No

   If Yes, has your Privacy Policy been through legal review? ☐ Yes ☐ No

4. Do you or a 3rd party perform privacy audits to confirm compliance with your Privacy Policy? ☐ Yes ☐ No

   If Yes, how often are audits performed? _____

5. Do you or a 3rd party conduct vulnerability assessments of your website? ☐ Yes ☐ No

Product or Service Cybersecurity

1. Do you have a comprehensive cybersecurity plan in place which identifies the vulnerabilities and/or threat sources which may permit the unauthorized: access, modification, misuse, or denial of use; or the unauthorized use of information that is stored, accessed or transferred from your product or service, to an external recipient and may impact patient safety? ☐ Yes ☐ No

   If Yes, does it include: (Check all that apply)

   ☐ Monitoring cybersecurity information sources for emerging vulnerabilities and risk

   ☐ Protocols for vulnerability intake and handling

   ☐ Defined process to detect and assess both the presence and impact of a vulnerability or threat

   ☐ Defined acceptable performance with respect to protecting, responding, and recovering from a cybersecurity risk

   ☐ A vulnerability disclosure policy and practice

   ☐ Deploying mitigations that address cybersecurity risk early and prior to exploitation

2. Do you incorporate the following into your product or service Risk Management protocols: (Check all that apply)

- ☐ Defined process for assessing the exploitability of a cybersecurity vulnerability
- ☐ Defined process to evaluate cybersecurity risk versus essential clinical performance of your product or service
- ☐ Defined process to determine whether or not the exploitation of an identified vulnerability can be categorized as an acceptable or unacceptable risk
- ☐ Defined process to communicate threats
- ☐ Defined process for assessing the severity impact to patient health of a cybersecurity vulnerability
- ☐ Defined requirements necessary to achieve device safety and effectiveness
- ☐ Defined process to systematically conduct risk evaluations and determine whether a cybersecurity vulnerability affecting your product or service presents an acceptable or unacceptable risk
- ☐ Protocols to establish, document, and maintain throughout the lifecycle of the product or service, an ongoing process for identifying hazards associated with cybersecurity

3. Do you incorporate the following into your product or services' cybersecurity remediation protocols:

(Check all that apply).

- ☐ Ensure the version for acquired software is supported by the vendor
- ☐ Protect web applications by deploying web application firewalls (WAFs) and non-webbased applications with specific application firewalls
- ☐ Ensure explicit error checking is performed and documented for all input on in-house developed software
- ☐ Test in-house-developed and 3rd party procured web applications for common security weaknesses prior to deployment and whenever updates are made
- ☐ System error messages are not displayed to end-users
- ☐ Maintain separate environments for production and nonproduction systems
- ☐ Use standard hardening configuration templates for applications that rely on a database
- ☐ Ensure software development personnel receive training in writing secure code for their specific development environment
- ☐ Ensure development artifacts are not included in deployed software or accessible in production environment for in-house developed applications

4. Have you had to make any "remediation actions" with regards to cybersecurity vulnerabilities in the past 3 years? ☐ Yes ☐ No

If Yes, were they successful? ☐ Yes ☐ No

<u>V. DATA BREACH</u> (Please complete this section if you are applying for Data Breach coverage)

General Security and Confidentiality Practices

1. Do you store, manage, utilize, transmit or otherwise handle Private Personal Data such as Protected Health Information, Social Security Numbers, Credit Card Numbers, Bank Account Numbers, etc. on:

(Check all that apply)

☐ Employees ☐ Vendors ☐ Customers

a. What is the approximate number of records retained? _____

b. Electronic ____% Paper ____%

2. Do you comply with Payment Card Industry (PCI) standards? ☐ Yes ☐ No

3. Do you have a Compliance Officer who is designated to ensure compliance with established institutional standards for handling data? ☐ Yes ☐ No

4. As part of your Cybersecurity Plan, do you have a written Data Security protocol which has been established and shared with all employees? ☐ Yes ☐ No

   If Yes, is this Data Security protocol updated at least bi-annually? ☐ Yes ☐ No

5. Are employee background checks, including criminal background checks, completed on employees who will have access to Private Personal Data? ☐ Yes ☐ No
6. Do you require employees to sign confidentiality agreements? ☐ Yes ☐ No
7. Do you have specific Data Security training, which includes specific sanctions up to termination for data security violations, for all employees? ☐ Yes ☐ No
8. Is the access to data files restricted to only need to know employees? ☐ Yes ☐ No
9. Do you have written and explicit policies in place to deal with a Data Breach? ☐ Yes ☐ No

   If Yes, have you tested that plan? ☐ Yes ☐ No

10. Do you outsource the data destruction of hard drives, media and tapes to 3rd parties? ☐ Yes ☐ No
11. Have the security practices of the company been audited without findings of deficiencies? ☐ Yes ☐ No

    If deficiencies have been identified, please detail the deficiencies and resolution on a separate sheet.

Paper Record Security Practices

1. Do you maintain paper records? ☐ Yes ☐ No

   If Yes, please complete the questions below.

   a. Do you have secure storage areas (e.g. locked rooms, locked file cabinets, limited access areas, etc.) for documents containing customer and/or employee Private Personal Data? ☐ Yes ☐ No
   b. Is access to such information restricted to only need to know employees? ☐ Yes ☐ No
   c. Do you have a sign out procedure when documents are removed from such areas? ☐ Yes ☐ No
   d. Do you have a written procedure for the secure transport of documents from one location to another? ☐ Yes ☐ No
   e. Do you have a regular document destruction policy? ☐ Yes ☐ No
   f. Do you supply shredding facilities/capabilities for paper documents? ☐ Yes ☐ No
   g. Do you outsource paper shredding and document destruction functions to 3rd parties? ☐ Yes ☐ No
   h. Do you have pre-coded dialing numbers in fax machines used for sending personal information? ☐ Yes ☐ No
   i. Do you restrict the removal of paper documents containing Private Personal Data from your premises? ☐ Yes ☐ No
   j. Describe any previous breaches and the steps taken to correct deficiencies:

_____

VI. MEDIA AND CONTENT (Please complete this section if you are applying for Media & Content coverage)

Intellectual Property

1. Do your intellectual property management procedures include the following? (Check all that apply)

   ☐ Acquisition of all rights, licenses, releases and consent for all content, products or services used or created by you or for you.

   ☐ Copyright and trademark searches and clearances conducted by a professional search firm or qualified legal counsel, which include the following checked items below:

   ☐ Domain names ☐ Product/service designs ☐ Designs or logos

   ☐ Legal review performed with respect to intellectual property laws in foreign jurisdictions.

☐ Legal review of the following checked items below performed prior to release, use or dissemination regardless of the medium.

☐ New technology used ☐ Products ☐ Content ☐ Advertising material

☐ Business methods ☐ Services ☐ Websites ☐ Marketing material

☐ Legal review of all updates or changes to the content, business methods and functionality of your website prior to dissemination or implementation.

☐ New hire and independent contract agreements include signed statements that new employees or contractors will not disseminate or use a previous employers' or clients' trade secrets or other intellectual property.

☐ Contractual acquisition of all rights (including electronic rights) to work done for you by third parties, including hold harmless and indemnification clauses, which inure to your benefit pertaining to that work.

☐ Legal review of all licensing and/or cross-licensing agreements.

☐ Annual audit to ensure your intellectual property management procedures are followed.

2. Do you provide any of the following? (Check all that apply)

☐ Applications/software that enables the copying or dissemination of the content of others (e.g. music, art, photos, graphics, video, written works, etc.)

☐ A file-swapping network ☐ Access to the file sharing activities (e.g. peer to peer)

Website Activities

3. With respect to your website activities, do your intellectual property management procedures include the following? (Check all that apply)

☐ Disclaimers on your website pertaining to the content made available or disseminated.

☐ Permissions from sites you link to or frame.

☐ Permission to use the trademarks and/or service marks of others.

☐ Legal review of the usage of trademarks and/or service marks of others.

VII. DECLARATION AND SIGNATURE

The undersigned, acting on behalf of all Applicants, declare that the statements set forth in this Application are true and correct and that thorough efforts were made to obtain requested information from each and every Applicant proposed for this insurance to facilitate the proper and accurate completion of this Application.

The undersigned agree that the information provided in this Application and any material submitted herewith are the representations of all the Applicants and are the basis for issuance of the insurance policy provided by us. Any material submitted with the Application shall be maintained on file (either electronically or paper) with us.

It is further agreed that:

- If any of the Applicants discover or become aware of any significant change in the condition of the Applicant Organization between the date of this Application and the policy inception date, which would render the Application inaccurate or incomplete, notice of such change will be reported in writing to us immediately;
- Any policy issued, will be in reliance upon the truthfulness of the information provided in this Application; provided, however, with respect to such information, no knowledge or information possessed by any Applicant shall be imputed to any other Applicants. If any person or persons knew as of the policy inception date that such information contained in the Application(s) were untrue, inaccurate or incomplete, then coverage may be denied or canceled with respect to that person or persons if such information was material to issuance of the policy. However, if the Chairperson of the Board of Directors, President, Chief Executive Officer, or Executive Director of the Applicant knew as of the policy inception date that such information contained in the Application(s) were untrue, inaccurate or incomplete, then coverage may be denied or canceled with respect to that person or persons and the Applicant Organization if such information was material to issuance of the policy;
- Statements in the Application, facts pertaining to or knowledge possessed by the individual signing the Application shall be imputed to the Applicant; and
- The signing of this Application does not bind the undersigned to purchase insurance.

This Application must be signed by a representative of the Applicant acting as the authorized representative of the person(s) and entity(ies) proposed for this insurance.

Date Signature/Title

_____

(Chief Executive Officer, President, Chief Financial Officer, Managing Partner or Owner)

Produced By: Agent: _____ Agency: _____

Agent Signature: _____

Agency Taxpayer ID or SS No.: _____ Agent License No.: _____

Address (Street, City, State, Zip): _____

VIII. FRAUD WARNINGS

Notice to Colorado Residents: It is unlawful to knowingly provide false, incomplete, or misleading facts or information to an insurance company for the purpose of defrauding or attempting to defraud the company. Penalties may include imprisonment, fines, denial of insurance, and civil damages. Any insurance company or agent of an insurance company who knowingly provides false, incomplete, or misleading facts or information to a policy holder or claimant for the purpose of defrauding or attempting to defraud the policy holder or claimant with regard to a settlement or award payable from insurance proceeds shall be reported to the Colorado Division of Insurance within the Department of Regulatory Agencies.

Notice to District of Columbia Residents: Warning: It is a crime to provide false or misleading information to an insurer for the purpose of defrauding the insurer or any other person. Penalties include imprisonment and/or fines. In addition, an insurer may deny insurance benefits if false information materially related to a claim was provided by the applicant. Notice to Florida Residents: Any person who knowingly and with intent to injure, defraud, or deceive any insurer files a statement of claim or an application containing any false, incomplete, or misleading information is guilty of a felony of the third degree.

Notice to Hawaii Residents: For your protection, Hawaii law requires you to be informed that presenting a fraudulent claim for payment of a loss or benefit is a crime punishable by fines or imprisonment, or both. Notice to Kentucky Residents: Any person who knowingly and with intent to defraud an insurance company or other person files an application for insurance containing any materially false information, or conceals for the purpose of misleading information concerning any fact material thereto, commits a fraudulent insurance act, which is a crime.

Notice to Arkansas, Louisiana & West Virginia Residents: Any person who knowingly presents a false or fraudulent claim for payment of a loss or benefit or knowingly presents false information in an application for insurance is guilty of a crime and may be subject to fines and confinement in prison.

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

Notice to Maine, Virginia, Tennessee & Washington Residents: It is a crime to knowingly provide false, incomplete or misleading information to an insurance company for the purpose of defrauding the company. Penalties include imprisonment, fines and denial of insurance benefits.

Notice to Michigan and Minnesota Residents: Any person who knowingly and with intent to defraud an insurance company or another person files an application for insurance containing any materially false information, or conceals for the purpose of misleading information concerning any fact material thereto, commits a fraudulent act, which is a crime and subjects the person to criminal and civil penalties.

Notice to Missouri & Arizona Residents: Claim Expenses are Inside the Policy Limits. All claim expenses shall first be subtracted from the limit of liability, with the remainder, if any, being the amount available to pay for damages.

Notice to Pennsylvania Residents: Any person who knowingly and with intent to defraud any insurance company or other person files an application for insurance or statement of claim containing any materially false information or conceals for the purpose of misleading, information concerning any fact material thereto commits a fraudulent insurance act, which is a crime and subjects such person to criminal and civil penalties.

Notice to New Mexico Residents: Any person who knowingly presents a false or fraudulent claim for payment of a loss or benefit or knowingly presents false information in an application for insurance is guilty of a crime and may be subject to civil fines and criminal penalties.

Notice to Ohio Residents: Any person who, with intent to defraud or knowing that he is facilitating a fraud against an insurer, submits an application or files a claim containing a false or deceptive statement is guilty of insurance fraud.

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

Notice to New Jersey Residents: Any person who knowingly includes any false or misleading information on an application for an insurance policy or files a statement of claim containing any false or misleading information is subject to criminal and civil penalties.

Notice to Oregon Residents: Any person who knowingly and with intent to defraud or solicit another to defraud any insurance company: (1) by submitting an application, or (2) by filing a claim containing a false statement as to any material fact, may be violating state law.

Notice to Vermont Residents: Any person who knowingly presents a false statement in an application for insurance may be guilty of a criminal offense and subject to penalties under state law.

The Hanover Insurance Group®

The Hanover Insurance Company
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The Agency Place (TAP)—https://tap.hanover.com

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