MISCELLANEOUS MEDICAL PROFESSIONAL & PRODUCTS LIABILITY INSURANCE APPLICATION

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

BACKGROUND INFORMATION – PLEASE READ:

1. Please type or print clearly.
2. Answer ALL questions completely leaving no blanks. If any questions, or part thereof, do not apply, print N/A in the space.
3. If additional space is needed to answer any questions fully, please attach a separate page.
4. This application must be completed, dated and signed by a Principal of the Applicant.

REQUIRED INFORMATION:

1. Loss History for the last TEN years. The loss run should be updated within the last 30 days and include a breakdown of total incurred losses (paid and reserves for both indemnity and expense), and a description of all losses, whether paid or outstanding (see appendix #3).
2. Most Recent AUDITED Financials.
3. Specimen copy of contractual agreements with independent contractor physicians and/or hospitals and/or labs.
4. Most recent local and/or State accreditation agency reports (if applicable).
5. Any marketing brochures or literature detailing services provided.

GENERAL INFORMATION:

a) Name of Applicant(s) _____

b) Address (City, State, Zip Code) _____

_____

_____

c) Telephone_____Fax_____Website_____
_____

d) Complete listing of insureds to be named under the policy (continue on a separate sheet if necessary) _____

_____

e) Additional insureds (explain relationship/ownership)
_____

_____

f) Full listing of locations (continue on a separate sheet if necessary) _____

_____

_____

_____

_____

g) Please list any acquisitions made in the last 5 years (include name of entity and date acquired)

_____

_____

_____

_____

_____

h) Are any acquisitions planned within the next 12 months? Y/N. If yes, please explain

_____

_____

i) Applicant is: (Individual/Partnership/Corporation/Joint Venture/LLC/Other – describe)

_____

j) For-profit/not-for-profit/publicly traded? If publicly traded please list exchange

_____

_____

k) Number of years applicant has been in operation

_____

l) List all states in which the applicant is operating. Is applicant licensed in the states in which it is operating? Y/N (If no please explain)

_____

_____

m) (i) Please provide a list of organisations by whom the applicant is either licensed or accredited

_____

_____

(ii) How long has the applicant held its license or accreditation?

_____

(iii) Has the applicant ever had its licence or accreditation revoked? Y/N If yes, please explain

_____

n) Audited Financial Information – please provide the following:

	Most Recently Audited Financial Year:	**Prior Financial Year:**
Total Assets:		
Net Assets/Equity:		
Long Term Debt (less current portion):		
Total Revenues:		
Net Revenues/Income:		
Total Cash and Cash Equivalents:		

PROFESSIONAL SERVICE/PRODUCT PROFILE:

a) Please state total number of patient contacts in the previous 12 months (if applicable). Please also clarify type of patient contact – e.g. obtaining a specimen by your staff, visit, procedure or treatment performed on a patient by your staff, encounters with clinical trial applicant, etc.

_____

_____

_____

_____

b)

For the previous 12 months please provide a FULL listing of the services and/or products provided,

and the percentage of total gross revenues. The total must equal 100%			
Assisted reproductive treatments/ techniques		Institutional review board	
Blood Gas		Manufacturing/Distribution/Packaging/ Mixing/Labelling	
Blood Transfusion		Microbiology	
Chemistry		Medical Devices	
Clinical Trials **- also see e) below**		Pathology	
Cytology		Parasitology	
Diagnostic Testing		Oncology/Radiotherapy treatment	
Drug Testing		Reproductive laboratory	
Drugs (Biological Dietary Supplements)		Research	
Endocrinology		Serology	
Genetics Testing		Surgical Monitoring	
Hematology		Sperm bank	
Histotechnology		Teleradiology	
Immunology		Urinalysis	
Information services/databases/software		Virology	
		Other (please explain)	
		TOTAL	**%**

c) IMPORTANT: Please provide on a separate sheet (see appendix # 1), a full narrative description of all the services/products listed above and any others which are provided by the applicant.

d) Does the applicant anticipate making any significant changes in the services/products provided within the next 12 months? Y/N. If yes, Please explain

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_____

_____

_____

e) IMPORTANT: If the applicant is involved in clinical trials, please complete the supplementary application rider (see appendix # 2)

MEDICAL STAFF PROFILE:

a) Please provide (on a separate sheet if necessary) a full listing of Employed Physicians on an FTE basis, complete with specialty

_____

_____

_____

b) Please provide details of all other staff utilised (on an FTE basis)

Health Professional	Employed (FTE)	Contracted (FTE)
RN's		
LPN's		
Pharmacist		

Medical Technician		
Pathologist		
Cytotechnologist		
Lab Technician		
Phlebotomist		
Other (please provide description)		

c) i) Does the applicant contract with other physician groups? Y/N. If yes, please provide total FTE count and specialities (on a separate sheet if necessary)

_____

_____

_____

ii) Are contracted physicians required to carry professional liability insurance? Y/N. If yes, please indicate minimum limits required

_____

_____

iii) Is the applicant named as an additional insured on the contracted physician's professional liability policy? Y/N

_____

BUSINESS CONTRACTS:

a)

Does the applicant have any contracts that do not contain the following provisions that inure to applicant's benefit? (Indicate Yes or No; if yes, please explain)	
All duties and responsibilities of each party	
Arbitration clause	
Choice of law or jurisdiction	
Force Majeure (extends to any and all events outside applicants control)	
Guarantees	
Hold harmless agreements/ indemnification	
Limitation of consequential damages	
Limitation of liabilities	
Warranty disclaimers	

b) In addition, does an attorney review all contracts or agreements including changes prior to use?

_____

_____

RISK MANAGEMENT, CLAIMS HANDLING & LOSS CONTROL

a) Does the applicant have a full time risk manager on staff? Y/N. If yes, please provide the following details:

Name _____

Title _____

Telephone _____

Qualifications _____

_____

Length of tenure at the applicant's organisation _____

b) Does the applicant have a formal, written risk management/loss prevention program? Y/N (please provide details, separately if necessary)

_____

_____

c) Does the applicant require new employees to participate in a training program that instructs them on all applicable company policies and procedures?

_____

_____

d) Does the applicant handle claims in-house or utilise the services of a third party administrator? (please provide details of in-house claims personnel/TPA used)

_____

_____

e) Do the applicant's marketing, sales, product development and regulatory teams receive regular training in product liability concepts and regulatory requirements? If yes, please provide details, or indicate N/A if not applicable

_____

_____

f) Does the applicant require legal counsel to review all marketing brochures and sales literature? If yes, please provide details, or indicate N/A if not applicable

_____

_____

CREDENTIALING:

a) Are all health professionals credentialed prior to hiring?

_____

b) Are physicians required to be board certified in their speciality?

_____

c) How often are physicians re-credentialed?

_____

d) Prior to hiring any employee, does the applicant verify:

i) Education background and training? Y/N

ii) Employment references with at least two previous employers? Y/N

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

_____

iv) Driving record? Y/N

v) Credit record? Y/N

vi) Drug tests? Y/N

e) Does the applicant keep all information on file and verify its completion prior to employment commencement? Y/N

LOSS HISTORY:

a) Please complete as Appendix # 3, an excel spreadsheet detailing all losses incurred within the last TEN years, including both paid and reserved amounts (indemnity and expense). The loss run should be updated within the last 30 days and include a brief description of each claim.

b) Please provide on a separate sheet, a detailed narrative description of all claims with a paid or incurred indemnity in excess of $50,000 within the past ten (10) years.

If applicable, please describe the steps which have been taken to mitigate the likelihood of a recurrence.

c) Please indicate any product or service which has been involved in class action litigation within the past ten (10) years

_____

_____

_____

d) Is the applicant aware of any circumstance(s) which may result in a claim being made against the Insured, which is/are not specified on the loss run? Y/N. If yes, please provide full details on a separate sheet.

_____

COVERAGE HISTORY:

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

Policy Period	Primary/Xs Limit	SIR/Deductible	Carrier	Annual Premium	Occurrence or Claims Made?	Retroactive Date

b) Has the applicant ever been declined or refused coverage, or had its coverage cancelled or non-renewed? Y/N. If yes, please explain

_____

_____

c) Has the applicant ever had its licence revoked, been subject to disciplinary action by any state or local authority or been subject to any fine, reprimand, or criminal penalty relating to the services provided? Y/N. If yes, please explain

_____

_____

_____

COVERAGE REQUEST:

Coverage	**Limits Requested**	**Deductible/SIR Requested**	**Retroactive Date Requested**
Professional Liability			
Products Liability			
General Liability			
Other (provide details)			

THE UNDERSIGNED IS AUTHORIZED BY THE APPLICANT AND DECLARES THAT THE STATEMENTS SET FORTH HEREIN AND ALL WRITTEN STATEMENTS AND MATERIALS FURINSHED TO THE INSURER IN CONJUNCTION WITH THIS APPLICATION ARE TRUE. SIGNING OF THIS APPLICATION DOES NOT BIND THE APPLICANT OR THE INSURER TO COMPLETE THE INSURANCE, BUT IT IS AGREED THAT THE STATEMENTS CONTAINED IN THIS APPLICATION, ANY SUPPLEMENTAL ATTACHMENTS, AND THE MATERIALS

SUBMITTED HEREWITH ARE THE BASIS OF THE CONTRACT SHOULD A POLICY BE ISSUED AND HAVE BEEN RELIED UPON BY THE INSURER IN ISSUING ANY POLICY.

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

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

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

WARNING

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

NOTICE TO FLORIDA APPLICANTS: "ANY PERSON WHO KNOWINGLY AND WITH INTENT TO INJURE, DEFRAUD, OR DECEIVE ANY INSURER FILES A STATEMENT OF CLAIM OR AN APPLICATION CONTAINING ANY FALSE, INCOMPLETE OR MISLEADING INFORMATION IS GUILTY OF A FELONY IN THE THIRD DEGREE."

NOTICE TO MAINE, TENNESSEE, VIRGINIA AND WASHINGTON APPLICANTS: "IT IS A CRIME TO KNOWINGLY PROVIDE FALSE, INCOMPLETE OR MISLEADING INFORMATION TO AN INSURANCE COMPANY FOR THE PURPOSE OF DEFRAUDING THE COMPANY. PENALTIES MAY INCLUDE IMPRISONMENT, FINES OR A DENIAL OF INSURANCE BENEFITS."

NOTICE TO PENNSYLVANIA APPLICANTS: "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 YORK AND KENTUCKY APPLICANTS: "ANY PERSON WHO KNOWINGLY AND WITH INTENT TO DEFRAUD ANY INSURANCE COMPANY OR OTHER PERSON FILES AN APPLICATION FOR INSURANCE OR STATEMENT OF CLAIMS CONTAINING ANY MATERIALLY FALSE INFORMATION, OR CONCEALS FOR THE PURPOSE OF MISLEADING, INFORMATION CONCERNING ANY FACT MATERIAL THERETO, COMMITS A FRAUDULENT INSURANCE ACT, WHICH IS A CRIME, AND SHALL ALSO BE SUBJECT TO A CIVIL PENALTY NOT TO EXCEED FIVE THOUSAND DOLLARS AND THE STATED VALUE OF THE CLAIM FOR EACH SUCH VIOLATION."

Signed:

_____

Must be signed by corporate officer with authority to sign on Applicant's behalf

Date:

Day	Month	Year

MISCELLANEOUS MEDICAL PROFRESSIONAL & PRODUCTS LIABILITY INSURANCE APPLICATION

APPENDIX #1: SUPPLEMENTAL NARRATIVE DESCRIPTION OF PRODUCTS/SERVICES

- **Refer to item c) of the Professional Service/Product Profile Section of the main application**
- **Use additional pages if necessary**

Product/Service	Full Description

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APPENDIX #2: CLINICAL TRIALS RIDER

- **Refer to item e) of the Professional Service/Product Profile Section of the main application**
- **Please provide a full listing of active trials currently being sponsored; use additional pages if necessary**

Product Name/ Protocol #	# of new Enrollees over next policy period	Trial Phase	Location

Please complete the following questions, indicating N/A where not applicable

a) Total number of completed human clinical trials sponsored in the last 3 years

_____

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

_____

c) Any clinical trials discontinued or suspended for safety reasons? (If yes, provide details)

_____

_____

d) Number of applicants' CRA's who have less than 5 years experience

_____

e) Which of the following are not required to meet the applicant's clinical investigator (CI) acceptability standards: formal training, accreditation, certifications, workload demand assessments, speciality and patient group expertise?

_____

_____

f) Have any of the applicants' CI's been cited for regulatory violations? If yes, provide details

_____

_____

g) Has applicant experienced any evidence of serious regulatory non-compliance or fraud by applicant's CI's and their staff in the past five (5) years? If yes, provide details

_____

_____

h) Please state number of Clinical trial "for cause audits" conducted by applicant, FDA, or OHRP in the last 3 years:

_____

i) Does the applicant use information videos as part of the informed consent process?

_____

j) Does the applicant perform a final approval of IRB approved informed consent documents?

_____

k) Is the applicant in compliance with the FDA requirements concerning financial disclosures?

_____

l) What has been the maximum compensation the applicant has offered trial participants?

_____

m) Is the applicant in compliance with applicable state regulations regarding human clinical trials?

_____

n) Do any of the applicant's employees provide direct patient care on the applicant's behalf? If so, do they carry their own medical malpractice insurance? Please specify limits

_____

o) Does the applicant ever act as both trial sponsor and clinical investigator?

_____

p) Does the applicant operate an inpatient facility? If yes, does the applicant have an accredited emergency care facility? Please provide details

_____

_____

_____