

NeitClem Wholesale Ins Brokerage Inc.  
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**APPLICATION FOR  
 CLINICAL RESEARCH  
 ORGANIZATIONS & CLINICAL  
 TRIALS FOR PROFESSIONAL AND  
 GENERAL LIABILITY INCLUDING  
 PRODUCTS LIABILITY INSURANCE  
 (Claims Made Basis)**

**APPLICANT'S INSTRUCTIONS:**

1. Answer all questions. If the answer requires detail, please attach a separate sheet.
2. Application must be signed and dated by owner, partner or officer.
3. Please do not complete application earlier than 45 days before proposed effective date of coverage.
4. PLEASE READ CAREFULLY THE STATEMENTS AT THE END OF THIS APPLICATION.  
 (PLEASE TYPE OR PRINT IN INK)

**1. APPLICANT INFORMATION**

- a. Full name of applicant:
- b. Principal office address:
- c. Number of Employees: Full time \_\_\_\_\_ Part time \_\_\_\_\_ Seasonal \_\_\_\_\_ Total \_\_\_\_\_
- d. Additional office locations:
- e. Name of parent company:
- f. Please describe all operations to be insured:
- g. Phone: ( ) \_\_\_\_\_
- h.  Corporation  Partnership  Joint Venture  Sole Proprietor  Other
- i. Date Established:

**2. APPLICANT OPERATIONS**

a. Fees and Receipts

Estimate for Current Year	Estimate for Next Fiscal Year
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Date: From \_\_\_\_\_ to \_\_\_\_\_ Dates: From \_\_\_\_\_ to \_\_\_\_\_

b. Percentage of foreign professional services and provide the names of the countries involved:

c. Do you manufacture or sell any products?  Yes  No

If Yes, please attach a detailed description of your current products and any future products being researched.

d. Please indicate the phase of testing for which you are seeking coverage: Phase

Please describe this phase:

(ii) Will this phase be performed in accordance with an FDA approved protocol?  Yes  No

If No, please explain.

(iii) Please indicate IND number:

(iv) Will this phase and have all previous related phases been performed in accordance with an FDA approved protocol?  Yes  No  
 If No, please explain.

e. Will you or your employees provide any health care services  
 If Yes:

Professional Title:

Description of services provided:

f. Is the clinical investigator an employee of your firm?  Yes  No

g. Is the clinical investigator an employee of the test site facility?  Yes  No

<p><b>2. APPLICANT OPERATIONS (CONTD.)</b></p> <p>h. (i) Please provide the name and the proposed use or function of the product being tested.</p> <p>(ii) Are you aware of any other approved uses or functions of the product being tested?      <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p style="padding-left: 20px;">If Yes, please attach a detailed explanation.</p> <p>(iii) Do you have any knowledge that this product or any of its components might cause or contribute to any immune system reactions?      <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p style="padding-left: 20px;">If Yes, please attach a detailed explanation.</p> <p>i. Please provide the name of the product manufacturer (if other than yourself):</p>	<p>f. How will the trial be conducted and by whom?</p> <p style="padding-left: 20px;">Please attach a detailed explanation.</p> <p>g. How will the trial be funded?</p> <p>h. Where will the trial be performed? Please check the appropriate response.</p> <p style="padding-left: 20px;"><input type="checkbox"/> Facility &amp; Location    <input type="checkbox"/> Non-Profit Testing Institute  <input type="checkbox"/> Clinical Research Center    <input type="checkbox"/> Other (please describe)</p> <p style="padding-left: 20px;">(Please attach a list if additional space is needed.)</p> <p>i. (i) Will an Institutional Review Board oversee the trials?      <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p style="padding-left: 20px;">(ii) Are you a member of this Board?    <input type="checkbox"/> Yes <input type="checkbox"/> No</p>																																																
<p><b>3. TESTING INFORMATION</b></p> <p>a. Please indicate the anticipated number of test subjects over the next 12 months:</p> <p>b. Please give the sex and age of the test subjects:</p> <p>c. How will test subjects be recruited?</p> <p style="padding-left: 20px;">Please provide a detailed explanation.</p> <p>d. Will test subjects be required to sign an informed consent document?      <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>e. The anticipated trial period:</p> <p style="padding-left: 20px;">From _____ To _____</p>	<p>j. Please indicate the number of employed professionals or independent contractors. (IF NONE, STATE NONE.)</p> <table style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 60%;"></th> <th style="width: 15%; text-align: center;"><u>Employee</u></th> <th style="width: 15%; text-align: center;"><u>Contractor Independent</u></th> <th style="width: 10%; text-align: center;"><u>Total</u></th> </tr> </thead> <tbody> <tr><td>(i) RN/LPN</td><td style="text-align: center;">_____</td><td style="text-align: center;">_____</td><td style="text-align: center;">_____</td></tr> <tr><td>(ii) Lab Tech.</td><td style="text-align: center;">_____</td><td style="text-align: center;">_____</td><td style="text-align: center;">_____</td></tr> <tr><td>(iii) Clinical Investigator</td><td style="text-align: center;">_____</td><td style="text-align: center;">_____</td><td style="text-align: center;">_____</td></tr> <tr><td>(iv) Clinical Research Assoc.</td><td style="text-align: center;">_____</td><td style="text-align: center;">_____</td><td style="text-align: center;">_____</td></tr> <tr><td>(v) Physician</td><td style="text-align: center;">_____</td><td style="text-align: center;">_____</td><td style="text-align: center;">_____</td></tr> <tr><td>(vi) Medical Monitor</td><td style="text-align: center;">_____</td><td style="text-align: center;">_____</td><td style="text-align: center;">_____</td></tr> <tr><td>(vii) Engineer</td><td style="text-align: center;">_____</td><td style="text-align: center;">_____</td><td style="text-align: center;">_____</td></tr> <tr><td>(viii) Biostatistician</td><td style="text-align: center;">_____</td><td style="text-align: center;">_____</td><td style="text-align: center;">_____</td></tr> <tr><td>(ix) Data Entry</td><td style="text-align: center;">_____</td><td style="text-align: center;">_____</td><td style="text-align: center;">_____</td></tr> <tr><td>(x) Legal Counsel</td><td style="text-align: center;">_____</td><td style="text-align: center;">_____</td><td style="text-align: center;">_____</td></tr> <tr><td>(xi) Other _____</td><td style="text-align: center;">_____</td><td style="text-align: center;">_____</td><td style="text-align: center;">_____</td></tr> </tbody> </table> <p>k. Do you perform any environmental testing or consulting?      <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p style="padding-left: 20px;">If Yes, please attach a detailed explanation.</p>		<u>Employee</u>	<u>Contractor Independent</u>	<u>Total</u>	(i) RN/LPN	_____	_____	_____	(ii) Lab Tech.	_____	_____	_____	(iii) Clinical Investigator	_____	_____	_____	(iv) Clinical Research Assoc.	_____	_____	_____	(v) Physician	_____	_____	_____	(vi) Medical Monitor	_____	_____	_____	(vii) Engineer	_____	_____	_____	(viii) Biostatistician	_____	_____	_____	(ix) Data Entry	_____	_____	_____	(x) Legal Counsel	_____	_____	_____	(xi) Other _____	_____	_____	_____
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<p><b>3. TESTING INFORMATION (CONTD.)</b></p> <p>I. Please indicate testing performed on specified products over the last 12 months and anticipated testing to be performed over the next 12 months:</p> <table style="width:100%; border-collapse: collapse;"> <thead> <tr> <th style="width:70%;"></th> <th style="width:15%; text-align: center;"><u>Last</u> <u>12 Months</u></th> <th style="width:15%; text-align: center;"><u>Next</u> <u>12 Months</u></th> </tr> </thead> <tbody> <tr><td>(i) Hormones &amp; Steroids</td><td>_____</td><td>_____</td></tr> <tr><td>(ii) Vaccines</td><td>_____</td><td>_____</td></tr> <tr><td>(iii) Injectables</td><td>_____</td><td>_____</td></tr> <tr><td>(iv) Prescription Products</td><td>_____</td><td>_____</td></tr> <tr><td>(v) Over the Counter</td><td>_____</td><td>_____</td></tr> <tr><td>(vi) Diet Aids</td><td>_____</td><td>_____</td></tr> <tr><td>(vii) Vitamins</td><td>_____</td><td>_____</td></tr> <tr><td>(viii) Food Supplements</td><td>_____</td><td>_____</td></tr> <tr><td>(ix) Novel Drugs</td><td>_____</td><td>_____</td></tr> <tr><td>(x) Generic Off-Patient</td><td>_____</td><td>_____</td></tr> <tr><td>(xi) Products, Other than Above</td><td>_____</td><td>_____</td></tr> <tr><td>(xii) Instruments (x-diagnostic)</td><td>_____</td><td>_____</td></tr> <tr><td>(xiii) Cosmetics, Health &amp; Beauty Aids</td><td>_____</td><td>_____</td></tr> <tr><td>(xiv) Surgical Equipment</td><td>_____</td><td>_____</td></tr> <tr><td>(xv) Diagnostic Instruments &amp; Equipment</td><td>_____</td><td>_____</td></tr> <tr><td>(xvi) Therapeutic Devices</td><td>_____</td><td>_____</td></tr> <tr><td>(xvii) Life Support</td><td>_____</td><td>_____</td></tr> <tr><td>(xviii) Other</td><td>_____</td><td>_____</td></tr> </tbody> </table>		<u>Last</u> <u>12 Months</u>	<u>Next</u> <u>12 Months</u>	(i) Hormones & Steroids	_____	_____	(ii) Vaccines	_____	_____	(iii) Injectables	_____	_____	(iv) Prescription Products	_____	_____	(v) Over the Counter	_____	_____	(vi) Diet Aids	_____	_____	(vii) Vitamins	_____	_____	(viii) Food Supplements	_____	_____	(ix) Novel Drugs	_____	_____	(x) Generic Off-Patient	_____	_____	(xi) Products, Other than Above	_____	_____	(xii) Instruments (x-diagnostic)	_____	_____	(xiii) Cosmetics, Health & Beauty Aids	_____	_____	(xiv) Surgical Equipment	_____	_____	(xv) Diagnostic Instruments & Equipment	_____	_____	(xvi) Therapeutic Devices	_____	_____	(xvii) Life Support	_____	_____	(xviii) Other	_____	_____	<p><b>5. CLAIMS</b></p> <p>(Attach a detailed explanation for any "Yes" answers)</p> <table style="width:100%; border-collapse: collapse;"> <tr> <td style="width:80%;"></td> <td style="width:10%; text-align: center;"><u>Yes</u></td> <td style="width:10%; text-align: center;"><u>No</u></td> </tr> </table> <p>a. Are you aware of any incidents or circumstances which are likely to result in claims against you under the coverage sought herein? <span style="float: right;">[ ] [ ]</span></p> <p>b. Have you ever been inspected, surveyed, or audited by the Food &amp; Drug Administration, the Center for Drug Evaluation and Research, or the Center for Biologics Evaluation and Research? <span style="float: right;">[ ] [ ]</span></p> <p>c. Have you ever been subject to any inquiry or investigation by any federal, state or local agency concerning your professional services? <span style="float: right;">[ ] [ ]</span></p> <p>d. Do you operate in compliance with the FDA's Good Clinical Practice Guidelines? <span style="float: right;">[ ] [ ]</span></p> <p>e. Have you ever been cited for any non-compliance of Good Clinical Practices or any federal state or local law, ordinance, directive or regulation? <span style="float: right;">[ ] [ ]</span></p>		<u>Yes</u>	<u>No</u>
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<p><b>4. APPLICANT HISTORY</b></p> <p>a. Provide a brief description of the results of any previous related trials:</p> <p>b. Fully describe any adverse results from previous related trials including animal studies and/or toxicity studies:</p> <p>c. List any claims related information provided in 4(a) and 4(b) above:</p> <table style="width:100%; border-collapse: collapse;"> <thead> <tr> <th style="width:10%;"></th> <th style="width:15%; text-align: center;"><u>Date</u></th> <th style="width:15%;"></th> <th style="width:15%;"></th> <th style="width:15%;"></th> <th style="width:15%;"></th> </tr> <tr> <th style="text-align: left;"><u>Claimant</u></th> <th style="text-align: center;"><u>of Loss</u></th> <th style="text-align: center;"><u>Expense</u></th> <th style="text-align: center;"><u>Indemnity</u></th> <th colspan="2" style="text-align: center;"><u>Nature of Injury</u></th> </tr> </thead> <tbody> <tr> <td> </td> <td> </td> <td> </td> <td> </td> <td colspan="2"> </td> </tr> </tbody> </table> <p>d. Year 2000:</p> <table style="width:100%; border-collapse: collapse;"> <tr> <td style="width:80%;"></td> <td style="width:10%; text-align: center;">YES</td> <td style="width:10%; text-align: center;">NO</td> </tr> </table> <p>(i) Does your computer system store a four-digit year? <span style="float: right;">[ ] [ ]</span></p> <p>(ii) If NO, please attach a description of corrective measures taken and the date upon which you anticipate the problem will be solved.</p>		<u>Date</u>					<u>Claimant</u>	<u>of Loss</u>	<u>Expense</u>	<u>Indemnity</u>	<u>Nature of Injury</u>									YES	NO	<p><b>6. COVERAGE</b></p> <p>a. Limits of liability desired: \$ _____</p> <p>b. Amount of deductible desired: \$ _____</p> <p>c. Present coverage</p> <table style="width:100%; border-collapse: collapse;"> <thead> <tr> <th style="width:20%;"></th> <th style="width:20%; text-align: center;">Prof./GL</th> <th style="width:20%;"></th> <th style="width:20%;"></th> <th style="width:20%;"></th> </tr> <tr> <th style="text-align: left;"><u>Carrier</u></th> <th style="text-align: center;"><u>Limits</u></th> <th style="text-align: center;"><u>Deductible/SIR</u></th> <th colspan="2" style="text-align: center;"><u>Claims Made?</u></th> </tr> <tr> <td> </td> <td> </td> <td> </td> <td style="text-align: center;"><u>Yes</u></td> <td style="text-align: center;"><u>No</u></td> </tr> </thead> <tbody> <tr> <td> </td> <td> </td> <td> </td> <td> </td> <td> </td> </tr> </tbody> </table> <p>If Yes, please provide an explanation.</p> <p>d. Retroactive date (if applicable) _____</p>		Prof./GL				<u>Carrier</u>	<u>Limits</u>	<u>Deductible/SIR</u>	<u>Claims Made?</u>					<u>Yes</u>	<u>No</u>																								
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**7. ADDITIONAL INFORMATION**

Please provide the following information with this application:

- (i) Advertisements, brochures, descriptive literature.
- (ii) Sample contract between you and the clinical trial investigator, if the investigator is not your employee or an employee of the test site facility.
- (iii) Informed consent document.
- (iv) Most recent Annual Report or audited financial statement
- (v) Copy of letterhead or other business stationary.

\* NOTICE TO APPLICANT: The coverage applied for is SOLELY AS STATED IN THE POLICY, which provides coverage on a "CLAIMS MADE" basis for ONLY THOSE CLAIMS THAT ARE FIRST MADE AGAINST THE INSURED DURING THE POLICY PERIOD unless the extended reporting period option is exercised in accordance with the terms of the policy.

WARRANTY: I/We warrant to the Insurer, that I understand and accept the notice stated above and that the information contained herein is true and that it shall be the basis of the policy of insurance and deemed incorporated therein, should the Insurer evidence its acceptance of this application by issuance of a policy.

\_\_\_\_\_  
Name of Applicant

\_\_\_\_\_  
Title (Officer, partner, etc.)

\_\_\_\_\_  
Signature of Applicant

\_\_\_\_\_  
Date

SIGNING this application does not bind the Applicant or the Insurer or the Underwriting Manager to complete the insurance, but one copy of this application will be attached to the policy, if issued.