

<b>Type/Clase :</b>	Contrat-type /Model contract /Modelo de contrato
<b>Source/Procedencia :</b>	Centre du Commerce International CNUCED/OMC International Trade Centre UNCTAD/WTO Centro de Comercio Internacional UNCTAD/OMC
	Palais des Nations 1211 Genève 10 Suisse
<b>Date de publication :</b>	01/02/2001
<b>Date of publication :</b>	
<b>Fecha de publicación :</b>	
<b>Tél/Tel :</b>	(41-22)730 01 11
<b>Fax :</b>	(41-22)733 44 39
<b>Web :</b>	www.intracen.org
✉	itcreg@intracen.org

**Avertissement:** Les contrats et guides de la présente collection ont été sélectionnés à seule fin d'illustration. Leur contenu et leur utilisation n'engagent pas la responsabilité de *Juris International*.

**Please note:** The contracts and guides contained in the present collection have been selected for illustrative purposes only. *Juris International* shall not be liable for their contents or use.

**Advertencia:** Los contratos y las guías de la presente colección han sido seleccionados únicamente a manera de ilustración. Su contenido y utilización no comprometen la responsabilidad de *Juris internacional*.

## **RESEARCH AGREEMENT (EXAMPLE)**

This Agreement is made this day of \_\_\_\_\_, 19 \_\_\_\_ (the "Agreement Date"), by and among CHEMICAL Formulations whose principal offices are at North Shore Drive 3600, Sarasota, Florida 01234, ("CHEMICAL"); and The University of Ghent <component>, whose address is <address of component> ("INSTITUTION"), (collectively "the Parties"). The Parties agree as follows:

### **ARTICLE I – Research Program**

1.1. – INSTITUTION shall use its best efforts to complete the clinical study (the "Study") entitled "<title>"; Study No. ##### in accordance with the protocol attached as Exhibit A (the "Protocol") and any amendments thereto. In addition, INSTITUTION shall conduct the Study in accordance with Good Clinical Practices and all federal, state and local laws and regulations, applicable to the Study.

1.2. – <Principal Investigator> ("Principal Investigator") will serve as the principal investigator, and will supervise and direct INSTITUTION's participation in the Study.

1.3. – INSTITUTION shall permit representatives of CHEMICAL or the United States Food and Drug Administration ("FDA") at reasonable times and in a reasonable manner to inspect the research facilities and all subjects' medical records and other records relating to the subject Agreement.

1.4. – In full consideration for INSTITUTION's work under this Agreement, CHEMICAL agrees to pay not more than \$<amount> subject to the following conditions.

1.4.1 – CHEMICAL will pay \$<amount> per evaluable subject and completed case report forms ("CRFs") acceptable to CHEMICAL, up to a maximum of evaluable subjects and acceptable CRFs. An evaluable subject is one who was properly entered into the Study under the Protocol, has adhered to the Protocol, and has completed the entire Study.

1.4.2. – CHEMICAL will make such payments according to the following schedule:

1.4.2.1. – \$<amount> as an initial payment in advance of the start of the Study;

1.4.2.2. – An additional \$<amount> after evaluable subjects have been completed and acceptable CRFs have been provided for these subjects; and

1.4.2.3. – An additional \$<amount> after evaluable subjects have been completed and acceptable CRFs have been provided for these subjects; and

1.4.2.4 – An additional \$<amount> after evaluable subjects have been completed and acceptable CRFs have been provided for these subjects; and

1.4.2.5 – An additional \$<amount> after evaluable subjects have been completed and acceptable CRFs have been provided for these subjects; and

1.4.2.6. – The final \$<amount> after all evaluable subjects have been completed, acceptable CRFs have been provided for all subjects, and the entirety of the data has been transferred to CHEMICAL for analysis.

1.4.3. – If a subject is withdrawn due to an adverse experience, CHEMICAL shall not be obligated to make a payment for that subject unless a final visit is performed and acceptable CRFs have been provided.

1.4.4. – Except as provided in Sub-Section 1.4.3 above, CHEMICAL shall not be obligated to make a payment for any subject who does not complete the entire study.

1.4.5. – CHEMICAL shall make all payments under this Section 1-4 by check payable to The University of Ghent <component>, Tax I.D. Number <tax i.d. #>, for delivery to INSTITUTION at the address provided in Section 6.1 below.

## **ARTICLE 2 – Term and Termination**

2.1. – This Agreement shall commence on the Agreement Date and shall continue in force for a period of months. At the end of the month period, CHEMICAL shall have the option to renew this Agreement for a period it chooses for up to one year under the same terms of this Agreement. Section 1.3 and Articles 3, 4, 5 and 6 shall survive termination of this Agreement.

2.2. – This Agreement may be terminated prior to completion of the Study as follows:

2.2.1. – CHEMICAL or INSTITUTION may terminate this Agreement immediately if required to halt the Study by FDA or compelled to do so by reasons of subject safety;

2.2.2. – CHEMICAL or INSTITUTION may terminate this Agreement at any time upon thirty (30) days, written notice;

2.2.3. – CHEMICAL or INSTITUTION may terminate this Agreement upon thirty (30) days' written notice in the event of a breach by the other party of its obligations under this Agreement and a failure by the other party to correct its breach(es) within that thirty (30) day notice period; or

2.2.4. – CHEMICAL or INSTITUTION may terminate this Agreement in the event that Principal Investigator can no longer serve as principal investigator and the Parties cannot agree upon an available, acceptable substitute.

2.3. – In the event of early termination of this Agreement, INSTITUTION shall immediately return any unspent and uncommitted portion of any payments made by CHEMICAL pursuant to Section 1.4. In the event of early termination of this Agreement by either party pursuant to Sub-Sections 2.2.2, or by 2.2.4, by CHEMICAL pursuant to Sub-Section 2.2.2, or by INSTITUTION pursuant to Sub-Section 2.2.3, CHEMICAL shall reimburse INSTITUTION for all reasonable expenditures on materials supported by invoices that were incurred prior to notice of termination, subject to the maximum amount to be paid under Section 1.4 above.

### **ARTICLE 3 - Confidentiality and Publication**

3.1. – Except as required by law, INSTITUTION and Principal Investigator shall retain CHEMICAL's information relating to products, know how, processes and practices which was disclosed to INSTITUTION or Principal Investigator ("Confidential Information") in strict confidence during the term of this Agreement and for seven (7) years thereafter, unless at some earlier time CHEMICAL consents to its disclosure or the information otherwise becomes generally available to the public through no breach of this Agreement by INSTITUTION or Principal Investigator. INSTITUTION and Principal Investigator represent and agree that only INSTITUTION employees who are bound by INSTITUTION Policies regarding treatment of Confidential Information (which is consistent with the obligations of this paragraph) shall be given access to Confidential Information or allowed to conduct the Study research.

3.2. – In the event that INSTITUTION or Principal Investigator proposes to publish any report, including abstracts or oral presentations, which contains information developed specifically as a result of the Study, such report shall be made available to CHEMICAL for its review at least thirty (30) days prior to submission for publication or presentation. CHEMICAL shall have the right to comment on the proposed report, and to make revisions in the proposed report necessary to protect Confidential Information or intellectual property which is owned jointly or solely by CHEMICAL. CHEMICAL shall review and notify the Principal Investigator of revisions promptly, but in no case later than thirty (30) days from the date of CHEMICAL's receipt of the proposed report. In the event that CHEMICAL determines that patent protection should be obtained for information contained in a proposed report, the submission of the proposed report shall be withheld at CHEMICAL's request until appropriate patent applications can be filed but in no case shall such delay exceed six (6) months from the date of submission of the report to CHEMICAL.

3.3. – In the event that the Study is a multiple site study, INSTITUTION and Principal Investigator shall not without CHEMICAL's prior written consent publish any report, including abstracts or oral presentations, prior to the publication of the report of the results of the entire multiple site study but in no event shall INSTITUTION be so restricted after the expiration of eighteen (18) months from completion of INSTITUTION's performance of the Study.

### **ARTICLE 4 - Indemnification**

4.1. – INSTITUTION represents and agrees that it is under no obligation to any third party that would interfere with its rendering to CHEMICAL the services described herein or be inconsistent with any of its representations or obligations under this Agreement. INSTITUTION represents that it has the authority necessary to consummate this Agreement.

4.2. – INSTITUTION shall, to the extent authorized under the Constitution and laws of the State of Texas, indemnify and hold CHEMICAL harmless from liability or loss resulting from the wrongful or negligent acts or omissions of INSTITUTION, or its agents or employees pertaining to the activities to be carried out pursuant to this Agreement; provided, however, that INSTITUTION shall not hold CHEMICAL harmless from claims arising out of the negligent, reckless or willful malfeasance of CHEMICAL, its officers, agents, or employees or any person or entity not subject to INSTITUTIONS supervision or control.

4.3. – CHEMICAL shall indemnify and hold INSTITUTION, The University of Ghent System, their Regents, officers, agents and employees harmless (collectively referred to as "University"), from and against liability or loss resulting from judgments or claims against them resulting from University's activities conducted pursuant to the Protocol, including but not limited to the use by CHEMICAL of the results of the Study; provided, however, that CHEMICAL's obligations under this section shall not be applicable to, and CHEMICAL shall not be responsible for any liability or loss arising out of: (a) University's failure to adhere to the terms of the Protocol, this Agreement or CHEMICAL's written instructions concerning the Study; (b) University's negligent acts or omissions, or reckless or willful misconduct or malfeasance; or (c) any claim or suit about which University does not notify CHEMICAL in writing promptly or as to which University does not at its own expense, and subject to the statutory duties of the Texas Attorney General, fully cooperate in the defense, including attending hearings and trials, securing and giving evidence, and obtaining the attendance of witnesses required by CHEMICAL. Upon receipt of notice, CHEMICAL and/or its insurer may retain counsel to appear and defend the claim or action and to assess its/their responsibility under this Agreement. University shall, at its own expense, and subject to the statutory duties of the Texas Attorney General, cooperate with CHEMICAL, its insurer and/or either or both of their counsel in defending any claim or action, shall use its best efforts to mitigate any losses or damages for which it may seek indemnity hereunder, and shall make no compromise or settlement of any claims or actions without the prior written consent of CHEMICAL. CHEMICAL, through its insurer, shall have the sole authority as to the settlement or litigation of any claim or action of which it receives notice.

## **ARTICLE 5 - Intellectual Property**

5.1. – Invention. The term "Invention" shall encompass any new process, system, formulation, article or manufacture, compound, composition of matter, use or apparatus, or any improvement thereon, whether patentable or unpatentable, made in connection with or arising out of the Study.

5.2. – Existing intellectual property. The inventions and technologies of CHEMICAL, INSTITUTION and Principal Investigator existing as of the Agreement Date are their separate property, respectively, and are not affected by this Agreement. None of the

Parties shall acquire any claims to or rights in such existing inventions or technologies of another of the Parties by virtue of this Agreement.

5.3. – CHEMICAL intellectual property. All rights and title to Inventions conceived and reduced to practice by employees of CHEMICAL shall belong to CHEMICAL and shall not be subject to the terms and conditions of this Agreement.

5.4. – Notice of Invention. INSTITUTION and Principal Investigator shall provide to CHEMICAL a written report describing any invention promptly after such invention is made or conceived.

5.5. – INSTITUTION Intellectual Property. The term "INSTITUTION Intellectual Property" shall refer to any Invention that is conceived and reduced to practice solely by one or more employees of INSTITUTION in conducting the Study, and not from CHEMICAL's Confidential Information provided to INSTITUTION and/or Principal Investigator in connection with the Study.

5.6. – Joint Intellectual Property. The term "Joint Intellectual Property" shall refer to any Invention of which one or more employees of INSTITUTION and one or more employees of CHEMICAL are joint inventors under the patent law ("Joint Intellectual Property"), which shall belong jointly to CHEMICAL and INSTITUTION.

5.7. – Option.

5.7.1. – INSTITUTION hereby grants CHEMICAL an option to negotiate an exclusive, worldwide, royalty-bearing license to make, use or sell under any Joint Intellectual Property. CHEMICAL shall have three (3) months from disclosure of any such Invention to notify INSTITUTION of its desire to enter into such an agreement, and an agreement shall be negotiated in good faith within a period not to exceed six (6) months from CHEMICAL's notification to INSTITUTION of its desire to enter into an agreement, or within such period of time as the parties shall mutually agree. If CHEMICAL and INSTITUTION fail to enter into an agreement during that period of time, the parties shall be entitled to exploit the Joint Intellectual Property in any manner consistent with their respective rights under the patent law.

5.7.2. – INSTITUTION agrees to grant to CHEMICAL an option to negotiate an exclusive or non-exclusive, worldwide, royalty-bearing license, to make, use or sell under any INSTITUTION Intellectual Property. CHEMICAL shall have three (3) months from disclosure of any invention or discovery to notify INSTITUTION of its desire to enter into such a license agreement, and a license agreement shall be negotiated in good faith within a period not exceed six (6) months from CHEMICAL's notification to INSTITUTION of its desire to enter into a license agreement, or within such period of time as the parties shall mutually agree. In the event that CHEMICAL and INSTITUTION fail to enter into an agreement during that period of time, then the rights to such inventions and discoveries shall be disposed of in accordance with INSTITUTION's policies, with no obligation to CHEMICAL. CHEMICAL agrees to pay a reasonable royalty to be negotiated in good faith for the use of any such INSTITUTION Intellectual Property. Until such invention or discovery has been presented as set forth above, INSTITUTION shall not offer rights to that invention or discovery to any third party.

5.7.3. – CHEMICAL may direct that a patent application or application for other intellectual property protection be filed with regard to INSTITUTION or Joint Intellectual Property. If CHEMICAL so directs, INSTITUTION shall promptly prepare, file and prosecute any U.S. and foreign applications in INSTITUTION's name, or cooperate in such preparation, filing and presentation in both parties' names in the case of Joint Intellectual Property, and CHEMICAL shall bear all costs incurred in connection with such preparation, filing, prosecution and maintenance of U.S. and foreign applications. If CHEMICAL subsequently decides to discontinue the financial support of the prosecution or maintenance of the application(s), INSTITUTION may at its discretion and own expense, prepare, file, prosecute or maintain any such patent(s) or patent application(s), but such patent(s) or patent application(s) shall not be subject to the option(s) in Section 5.7.1 and 5.7.2 of this Agreement.

## **ARTICLE 6 - General Provisions**

6.1. – Notices under this Agreement shall be in writing and shall be deemed to be given when delivered by hand or by express service, sent by telex or telecopier (provided such is promptly confirmed by airmail), or mailed by registered or certified airmail and, if intended for CHEMICAL, addressed to:

Scott B. Phillips, M.D.  
Director, Drug Discovery, CHEMICAL Corporation  
600 Knightsbridge Parkway, Lincolnshire, Illinois 60069

if intended for INSTITUTION, addressed to:

<component's address>

and, if intended for Principal Investigator, addressed to:

<Principal Investigator's address>

6.2. – Headings. Article and Section headings used in this Agreement are inserted for convenience of reference only and shall not effect the construction or interpretation of the respective Articles and Sections.

6.3. – Validity. If any provision of this Agreement is or becomes invalid, is ruled illegal by any court of competent jurisdiction, or is deemed unenforceable under then current applicable law from time to time in effect during the term of this Agreement, such provision shall be deemed deleted from this Agreement and replaced by a valid and enforceable provision which so far as possible achieves the parties' intent in agreeing to the original provision. The remaining provisions of this Agreement shall continue in full force and effect.

6.4. – Waiver. Any waiver, whether express or implied, by any of the Parties of a breach by another party, shall not operate as a waiver of future breaches of the same or a different character.

6.5. – Counterparts. This Agreement may be executed by the parties in counterparts, which together shall constitute one agreement.

6.6. – Amendments and Assignments. Any amendments to this Agreement must be in writing signed by authorized representatives of all parties. The rights and obligations under this Agreement shall not be assignable by INSTITUTION or Principal Investigator without CHEMICAL's prior written consent.

6.7. – Further Assurances. Each party agrees to use reasonable and practical efforts to perform any further acts and execute and deliver any and all further documents or instruments which may be reasonably necessary or desirable to carry out the provisions of this Agreement.

6.8. – Independent Contractors. INSTITUTION, Principal Investigator and CHEMICAL shall not be deemed to be partners, joint venturers, or each other's agents, and no party shall have the right to act on behalf of any other except as expressly provided for under this Agreement or otherwise expressly agreed upon in writing.

University of Ghent \_\_\_\_\_

By: \_\_\_\_\_  
Name

Title: \_\_\_\_\_

Date: \_\_\_\_\_

CHEMICAL Corporation

By: \_\_\_\_\_  
Name

Title: \_\_\_\_\_

Date: \_\_\_\_\_

I have read this Agreement and understand my obligations hereunder.

By: \_\_\_\_\_  
(Principal Investigator)