

 denotes sections that have been amended from the VCHC 10.0-HLS Repro/Develop Agreement w/ Huntingdon (attached)

AGREEMENT

between

CHEMICAL MANUFACTURERS ASSOCIATION

and

HUNTINGDON LIFE SCIENCES, INC.

CMA REFERENCE NUMBER:

VCHC - HLS ~~SATELLITE~~

I. SCOPE AND PARTIES

1. The parties to this Agreement are Huntingdon Life Sciences, Inc., the Research Contractor (Contractor), and the Chemical Manufacturers Association (CMA).
2. CMA will be represented during this Agreement by **Wendy K. Sherman**, the Vinyl Chloride Panel Manager. All communications with CMA shall be directed to the Panel Manager.
3. The Contractor agrees to perform in the manner described in the attached protocol, dated **February 17, 1997**, which is incorporated by reference and expressly made part of this Agreement:

Studies to Evaluate the Formation and Repair of DNA Adducts Induced in Adult and Neonatal CD Rats by Vinyl Chloride.

4. Changes in this Agreement must be authorized in writing by the Panel Manager, and any increase in cost must be authorized in writing by CMA's Treasurer or Controller. Unless otherwise provided in the written authorization of change, no such change shall affect the due dates of any progress, draft or final reports due under this Agreement.
5. The Contractor shall not make any changes in the protocol attached to this Agreement without written authorization from the Panel Manager, except that where such changes must be implemented before written authorization is

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practicable, the Panel Manager may give the required authorization orally, with a written confirmation following within five (5) working days.

6. The Contractor will employ the staff, oversee the personnel, provide the facilities and have exclusive control over its employees and the expenditures of funds authorized by CMA in this Agreement. The Contractor will be an independent contractor in the performance of this Agreement. Before subcontracting or assigning any portion of the work, the Contractor will obtain CMA's written approval. No such approval will relieve the Contractor from any of its obligations under this Agreement. The Contractor agrees to bind each of the subcontractors to the provisions of this Agreement.
7. CMA enters into this Agreement with the understanding that the project will be personally supervised by Raymond E. Schroeder. If this should change, the Contractor agrees to notify CMA in advance, in which event the Agreement becomes subject to renegotiation at CMA's option.
8. This Agreement becomes effective upon its execution and will remain in effect until all of its provisions have been implemented or until terminated by CMA pursuant to paragraph 31.29

II. TERMS OF PAYMENT

9. The total cost to CMA for this Agreement shall not exceed \$48,092.

For the performance of this Agreement by the Contractor, CMA shall make payments as follows:

- (a) \$24,092 payable following execution of this Agreement.
 - (b) One payment of \$12,000 payable ^{following} ~~upon~~ completion of the in-life portion of the study, and submission of a draft of the in-life portion of the study to Dr. James Swenberg and CMA.
 - (c) In no event will payments totaling more than \$36,092 be made prior to receipt by Dr. Swenberg and CMA of a copy of the final report for the in-life portion of the study.
 - (d) Final Payments – One payment of \$12,000 ^{following} ~~upon~~ receipt and acceptance by Dr. Swenberg and CMA of the final report for the in-life portion of the study.
10. Foreign travel costs are allowable only when each foreign trip has received the specific prior approval of the Panel Manager and is specified in the attached protocols. For purposes of this provision, foreign travel is defined as any travel outside the country of the Contractor's residence.

ESSENCE IN THE PERFORMANCE OF THIS AGREEMENT.

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III. PRESENTATION OF STUDY RESULTS

- ~~11. All correspondence and invoices concerning this project will be sent to CMA. The in-life portion of the study report will be sent to Dr. Swenberg with a copy to CMA. All submissions to CMA shall be in English and shall contain the CMA Reference Number VCHC - HLS - SATELLITE.~~
12. CMA and the Contractor agree to full public disclosure of scientific information contained in the CMA-accepted final reports developed through this Agreement. However, CMA reserves the right of first publication. The Contractor shall not release such information without prior CMA knowledge and review. If patentable discoveries ensue, these shall be declared in the public domain without any retention of proprietary interest.
13. The Contractor's scientific conclusions and professional judgments arising out of performance of the project will be the responsibility of the Contractor. The Contractor, however, will not publish or otherwise release data, conclusions, or manuscripts in a citable or quotable form without prior CMA knowledge and opportunity to comment. CMA opportunity to comment is for the purpose of clarification and format or editorial comments, but not for the purpose of substituting CMA's opinion for that of the Contractor.
14. The testing described in the protocol shall commence on or about May 5, 1997, and be completed according to the following schedule:
- | | |
|-------------|---------|
| Study No. 1 | 5/22/97 |
| Study No. 2 | 6/8/97 |
| Study No. 3 | 6/11/97 |
| Study No. 4 | 5/20/97 |
- Handwritten notes and signatures:*
- "15 JUL 97" and "STILL" with a signature.
- A large oval stamp containing "Huntingdon Life Sciences" and "Contract No. 118146".

If the testing will not be completed within the time specified, the Contractor must submit a written request for CMA approval of a new completion date and must include in this request a justification for the extension. Such requests should be made as soon as the need for additional time is evident. Except where it is impracticable, however, no request for additional time shall be made less than thirty (30) days before the original completion date.

~~No written progress reports will be required for this study.~~

15. The Contractor will provide Dr. Swenberg and CMA with one unbound original and two copies of the draft final report for the in-life portion of Studies No. 1 - 4 by July 31, 1997.

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Dr. Swenberg and CMA will provide comments to the Contractor within 30 days of its receipt of the draft report. Within 30 days from receipt of any comments on the draft final reports, the Contractor will provide one unbound original and two copies of the final report to Dr. Swenberg and CMA. At the same time, the Contractor will provide a written response to any comments which are not incorporated in the final report. The final report will identify the objectives of the study, describe the methodology employed, and record essential data.

16. The Contractor recognizes that test sponsors have a time sensitive obligation to report factual information regarding substantial adverse health or environmental effects. If the Contractor discovers findings indicating substantial risk to health or the environment during the course of the Study, the Contractor agrees to notify the Panel Manager promptly by telephone or facsimile, and if so requested shall provide a follow-up letter within five (5) working days, AND A FACSIMILE CONTAINING ESSENTIAL DATA WITHIN ^{TWENTY-FIVE} (25) HOURS. ✓

IV. QUALITY ASSURANCE

17. CMA staff, representatives of sponsoring companies, and consultants retained by CMA, as designated by the Panel Manager, will have reasonable access to the Contractor's personnel and facilities engaged in the work covered by this Agreement.
18. CMA may designate one or more consultants who may observe or audit the conduct of the work by this Agreement. The Contractor shall cooperate fully with such observations and audits.
19. The Contractor shall comply with all U.S. Government regulations in existence at the time of the Agreement. The conduct of these studies are not intended to meet or exceed any particular guidelines, including EPA's TSCA Good Laboratory Practices.

V. DATA RETENTION

- note: dropped original paragraphs 20 + 21 entirely non-GLP study*
20. All ~~records~~ raw data or other documentation relating to the testing covered by this Agreement shall be retained by the Contractor for a period of at least ten (10) years from the date of conclusion of the test or until such time as CMA shall designate in writing.
21. The materials retained pursuant to paragraph ²⁰ 22 shall be stored in an archive which ensures that they will be maintained in a safe and secure manner and allows for their expeditious retrieval when needed. Material retained in the archive shall be indexed by test substance, date of study, test system and nature of study. In the event that the Contractor or its archiving facility discontinue operations, all raw data, specimens and other documentation pertaining to the testing covered by this

Agreement shall be transferred to such other facility as CMA may direct. CMA shall be notified in writing of such a transfer.

VI. DATA DISCLOSURE

22. The Contractor will enter into a reasonable agreement for the protection of confidential business information with CMA, sponsoring companies, or any of their representatives who request such an agreement.
23. The Contractor will immediately notify CMA of any private or governmental request for information on ongoing or completed testing conducted under this Agreement, including any subpoena or other legal instrument requesting information. The Contractor will cooperate fully with any effort by CMA to narrow the scope of any such request, to obtain a protective order limiting the use or disclosure of information, or to obtain continued protection of the confidentiality of data provided by CMA. In any such effort, the Contractor shall be entitled to be represented by Counsel of its choice. CMA and the Contractor shall share reasonable expenses in connection with any joint actions taken in response to any compulsory process.
24. Notwithstanding the provisions of the previous paragraph, the Contractor shall permit duly designated government inspectors to inspect the Contractor's facilities at reasonable times and in a reasonable manner. CMA shall have the right to be present during any governmental inspection of the Contractor's facilities which relates to the research covered by this Agreement, although the inability of a CMA representative to attend such an inspection shall not be grounds for denying access to duly authorized government officials. ~~Within five (5) working days the Contractor shall provide CMA with copies of any data or other materials furnished to the government during an inspection of the Contractor's facilities.~~ The Contractor shall also immediately advise CMA by telephone or facsimile of the findings and observations of Government inspectors and provide CMA with a copy of any written inspection report received by the Contractor.
25. The Contractor shall not discuss the details of any ongoing or completed CMA-funded research projects in connection with any advertising or promotional literature without the prior written approval of CMA.

VII. MISCELLANEOUS PROVISIONS

26. The Contractor agrees to indemnify, and hold harmless CMA, ~~against~~ ^{AND ANY SPONSORING COMPANY FROM ANY AND} all claims, Penalties, liabilities, losses, damages and expenses, of every character whatsoever, for bodily injury, sickness and/or disease, including death, at any time resulting therefrom, sustained by any employee of Contractor while in, on or in any way connected

with this Agreement or with Contractor's performance thereunder, except to the extent such injury, sickness and/or disease is due to any negligence on the part of CMA, its employees or agents. ~~Insert Change A~~

27. The Contractor shall indemnify CMA and its members and their respective officers, directors and employees, from any loss, cost, damage or expense from any lawsuit, action, claim, demand or proceeding by Contractor's employees or others arising out of Contractor's negligent acts giving rise to any personal injury, death or property damages occurring during the time services are conducted. Contractor ~~will not indemnify CMA against any loss, cost or damage resulting from any claim arising out of CMA's use of any study conducted hereunder or its use or marketing of any substance which is the subject of any such study unless such claim is directly attributable to CMA's negligence or willful misconduct.~~ ~~SEE CHANGE A~~ ?

28. The Contractor agrees, if requested by CMA, to appear as a witness before, or prepare a written statement for, a court, regulatory agency or other organization regarding any matters connected with this Agreement. In the event of such a request by CMA, the Contractor's fees for such testimony will be negotiated; the Contractor's fees, however, will not exceed the fees the Contractor usually charges for such professional consultation.

29. CMA may terminate any or all of the studies covered by this Agreement by giving thirty (30) days notice of termination to Contractor. Upon receipt of such notice the Contractor will cease incurring costs on the study or studies except with the prior written approval of CMA for such costs as are necessary to close out the study. In the event of such termination, CMA's sole obligation shall be payment of all invoices issued up to the date of termination, the invoice for work performed subsequent to the last invoice date and prior to receipt of notice of termination, and the invoice for work carried out with the written approval of CMA subsequent to receipt of the notice of termination. In no event shall payments exceed the maximum amount of the agreed costs for the study or studies covered by this Agreement, together with a fee to be negotiated in good faith but which in no event exceeds 5% of the value of the studies canceled, in order to cover the opportunity cost of Contractor's inability to find alternative work for the facility assigned the CMA studies.

New Paragraph

30. This Agreement and the attached protocol represent the entire contract on this subject between the parties. There are no oral or written promises, terms, conditions, or obligations other than those contained herein; and this Agreement supersedes all previous communications, representations or agreements, either oral or written, between the parties on this subject. ~~Insert P 33 of our 1st SATELLITE~~ • SEE CHANGE (B)

31. This Agreement is subject to, and is to be construed under, the laws of the Commonwealth of Virginia, United States of America. Actions under this Agreement shall be brought in any court of competent jurisdiction in the Commonwealth of Virginia.

32. This Agreement may be amended only by a written addendum signed by the Contractor and CMA.
33. The obligations imposed under this Agreement shall apply to the legal successors and assigns of the Contractor, including any acquirers of all or substantially all of the assets of the Contractor, and of CMA.

Attachment:

Studies to Evaluate the Formation and Repair of DNA Adducts Induced in Adult and Neonatal CD Rats by Vinyl Chloride (FEBRUARY 17, 1997)

ACCEPTED FOR:

Huntingdon Life Sciences, Inc.

Name Signed

Name Typed

Title

Date

ACCEPTED FOR:

Chemical Manufacturers
Association, Inc.

Name Signed

Raymond J. O'Bryan
Name Typed

Controller
Title

Date

CMA 118150