

AGREEMENT
between
CHEMICAL MANUFACTURERS ASSOCIATION
and
APPLIED EPIDEMIOLOGY, INC.

CMA REFERENCE NUMBER:
VCHC-4.0-EPI-UPDATE

I. SCOPE AND PARTIES

1. The parties to this Agreement are Applied Epidemiology, Inc., a Massachusetts corporation whose address is P.O. Box 2424, Amherst, Massachusetts, 01004-2424, the Research Contractor (Contractor), and the Chemical Manufacturers Association (CMA), a New York corporation whose address is 2501 M Street, N.W., Washington, D.C., 20037, on behalf of the Vinyl Chloride Panel.
2. CMA will be represented during this Agreement by Hasnukh Shah, the 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 technical and administrative proposals which are expressly made part of this Agreement:

Update of Mortality Among Vinyl Chloride Workers for the Chemical Manufacturers Association, Revised Technical Proposal, January 3, 1995.

Update of Mortality Among Vinyl Chloride Workers for the Chemical Manufacturers Association, Revised Administrative Proposal, February 16, 1995.
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 the interim reports, the draft report or the final report under this Agreement.
5. The Contractor shall not make any changes in the technical proposal attached to this Agreement without written authorization from the Panel Manager, except that where such changes must be implemented before written authorization is 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, which shall not be unreasonably withheld or delayed. 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 Kenneth A. Mundt, Ph.D. 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 either party pursuant to paragraph 30.

II. TERMS OF PAYMENT

9. The total cost to CMA for this Agreement shall not exceed \$346,225.

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

- (a) \$67,045 payable upon the execution of this Agreement.
- (b) Six payment(s) of \$36,875 payable upon receipt and acceptance of the interim reports and the protocol required in paragraph 16.
- (c) One payment of \$26,818 payable upon receipt of a draft of the final report required in paragraph 17.
- (d) In no event will payments totaling more than \$315,113 be made prior to the final payment.
- (e) Final Payment -- A payment of \$31,112 upon receipt and acceptance by CMA of the final report, and an invoice labeled "final." This final payment includes a payment of \$11,000 for the cost of storage of all data, including raw data, for a period of ten years from the date of the final report. The Contractor will store all data pursuant to paragraphs 22 and 23. If data are transferred to a third party based on a written request from CMA prior to the ten year storage period, the Contractor will refund to CMA the remainder of the \$11,000 fund that has not been committed in a legally binding form to the storage facility. If at the end of the ten year storage period, CMA decides to store the data for any additional period, the Contractor and CMA will negotiate a cost for the additional storage. In no event will the Contractor destroy any data at the end of the storage period without prior written consent from CMA.

CMA may withhold payment if the Contractor fails to perform according to the terms of the Agreement.

10. Foreign travel costs are allowable only when each foreign trip has received the specific prior approval of the Panel Manager or is specified in the attached technical proposal. For purposes of this provision, foreign travel is defined as any travel outside the country of the Contractor's residence.
11. Time is of the essence in the performance of this Agreement.

III. PRESENTATION OF STUDY RESULTS

12. All correspondence, reports, invoices, and manuscripts concerning this project will be sent to CMA. All submissions to CMA shall be in English and shall contain the CMA Reference Number VCHC-4.0-EPI-UPDATE.
13. CMA and the Contractor agree to full public disclosure of scientific information contained in the CMA-accepted final report and manuscript 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.
14. 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.
15. As described in the administrative proposal, the research described in the technical proposal shall commence on or about April 1, 1995 and be completed, including the final report, by April 1, 1997. If the research 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.

The Contractor's obligations shall in any event be conditioned on the full cooperation of CMA and the timely providing by CMA of all information or services required of it. Should CMA fail to provide any information or to perform any act required of it hereunder within the time permitted therefor as may be specified herein, or in the attached technical and administrative proposals, the time for performance of the Contractor's services shall be extended by the delay caused by such failure or performance, such time to be at least equal to the number of days by which CMA has exceeded the permitted time and performance of its obligations. Should such delays in aggregate, cause delays and postpone deliverable dates in Paragraph 16 by the Contractor beyond six months as a result of CMA not providing necessary information to meet the deliverables, the Contractor may, at its option, terminate this Agreement prior to completion. The Contractor, however, will provide CMA with a 30 day advance written notice prior to the cancellation.

16. The Contractor will furnish progress reports and invoices as follows:

<u>Deliverable and Invoice Date</u>	<u>Deliverable</u>	<u>Invoice Amount</u>
04-1-95	Signed Contract	\$67,045
07-1-95	Progress Report 1	\$36,875
08-1-95	Cohort Verification & Protocol	\$36,875
11-1-95	Progress Report 2	\$36,875
03-1-96	Progress Report 3	\$36,875

07-1-96	Progress Report 4	\$36,875
11-1-96	Progress Report 5	\$36,875
01-1-97	Draft Report & Draft Manuscript	\$26,818
04-1-97	Final Report and Manuscript	\$31,112

Progress reports will describe any circumstances occurring during the reporting period that may affect the quality or integrity of the research results. As part of each progress report, the Contractor will discuss the timetable for completion of the work, including an assessment of the progress to date compared with the proposed schedule, and an outline of future plans. This discussion will identify any delays that have occurred or are expected in the completion of the critical tasks which may affect the timely completion of the work and explain the reasons for the delays.

17. The Contractor will provide CMA with one unbound original and two copies of a draft of the final report and draft manuscript on January 1, 1997, and CMA will provide comments within the scope of the study to the Contractor within 30 days of its receipt of the draft report. Within sixty (60) days from the receipt of any CMA comments on the draft of the final report, the Contractor will provide CMA with one unbound original and two copies of the final report and the final manuscript. At the same time, the Contractor will provide a written response to any CMA comments which are not incorporated in the final report. The final report will identify the objectives of the study, describe the methodology employed, record essential data, describe the statistical methods used to analyze the data, and discuss the study's results and conclusions.
18. The Contractor recognizes that study 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, and if so requested shall provide a follow-up letter within five (5) working days and a facsimile containing essential data within 24 hours.

IV. QUALITY ASSURANCE

19. 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. Requests for access to Contractor's personnel and or facilities shall be forwarded to and approved by Dr. Mundt or his designee.
20. 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.
21. The Contractor shall conduct the study according to the Guidelines for Good Epidemiology Practices for Occupational and Environmental Epidemiologic Research, published by the Chemical Manufacturers Association Epidemiology Resource and Information Center in 1991.

V. DATA RETENTION

22. All records, raw data or other documentation relating to the study covered by this Agreement shall be retained by the Contractor for a period of at least ten (10) years from the date of the final report and manuscript or until such time as CMA shall designate in writing.
23. The materials retained pursuant to paragraph 22 shall be stored in a storage facility 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 storage facility shall be indexed by study substance, date of study, study system and nature of study. In the event that the Contractor or its storage facility discontinue operations, all raw data and other documentation pertaining to the study 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

24. 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. Such an agreement is attached as Exhibit A and may be completed when appropriate.
25. The Contractor will immediately notify CMA of any private or governmental request for information on ongoing or completed research 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.
26. 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. The Contractor shall immediately 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 of the findings and observations of Government inspectors and provide CMA with a copy of any written inspection report received by the Contractor.
27. 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

28. The Contractor, by entering into this Agreement, agrees to protect, defend, indemnify, and hold CMA harmless from any and all claims against CMA for property damage, personal injury or death which arise out of or in connection with the negligent performance of this Agreement or any testing or research conducted pursuant hereto, or any intentional wrongful act committed by the Contractor. The Contractor, however, shall not be liable for such claims to the extent that they arise out of the negligence of CMA. The Contractor will carry comprehensive liability insurance in an amount adequate to cover the performance of this Agreement.
29. 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.
30. CMA may terminate the Agreement with 30 days advance written notice to the Contractor. In such event, the Contractor will present to CMA a detailed accounting of costs, including reasonable and necessary expenses incurred in terminating the project in an appropriate manner and in providing for the proper storage of the raw data from the completed portion of testing for a period of time agreed to at termination. CMA's financial liability to the Contractor will be limited to the actual cost incurred plus 10% overhead expenses plus 10% cancellation fee, not to exceed the total contract cost. In the course of such termination, the Contractor shall make every effort to submit to CMA all data and information relevant to the activities accomplished prior to the date of termination. To the extent requested by CMA, the Contractor will supply a detailed report of results to the date of termination. Additional payment by CMA, or return of unused funds by the Contractor, is limited by the provisions of paragraph 9, consistent with the results of such detailed accounting and the provisions of this Agreement.

In the event that CMA will (i) cause a delay in the completion of the Project beyond the time permitted under paragraph 15 above; or (ii) fail to cure within 30 days following written notice thereof any breach of a material term or provision of this Agreement prior to completion of the Project by the Contractor, Contractor may terminate this Agreement with 30 days advance written notice to CMA. Upon delivery of such notice of the Contractor to CMA, this Agreement shall terminate and become null and void without further recourse by the parties hereto; provided, however, that the Contractor shall be entitled to recover, within 30 days of the date of such termination, an amount equal to the value of the time expended and costs incurred by the Contractor in rendering services on the Project through the date of termination plus 10% overhead expenses plus 10% cancellation fee, not to exceed the total contract cost. Additional payment by CMA, or return of unused funds by the Contractor, is limited by the provisions of paragraph 9, consistent with the results of such detailed accounting and the provisions of this Agreement.

31. This Agreement, Exhibit A to the Agreement, and the attached technical and administrative proposals 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.

32. This Agreement is subject to, and is to be construed under, the laws of the District of Columbia, United States of America. Actions under this Agreement shall be brought in any court of competent jurisdiction in the District of Columbia.
33. This Agreement may be amended only by a written addendum signed by the Contractor and CMA.
34. 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.
35. **Warranty; Disclaimer; Limitation of Liability.** Contractor represents and warrants that the analysis, data, programs, and services to be delivered or rendered hereunder to CMA will be of the kind and quality designated and will be performed by qualified personnel. **CONTRACTOR MAKES NO OTHER WARRANTIES, EITHER EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION, ANY WARRANTY OF FITNESS FOR ANY PARTICULAR PURPOSES OR MERCHANTABILITY.** In no event shall Contractor be liable for special or consequential damages, either in contract or tort, whether or not the possibility of such damages has been disclosed to Contractor in advance or could have been reasonably foreseen by Contractor, except Contractor may be liable for such damages as a result of negligent, grossly negligent or intentional errors or omissions in the performance of Contractor's obligations* In the event of any error or omission that is not considered negligent, grossly negligent, or intentional, Contractor's sole liability to CMA hereunder shall be to furnish corrected reports or data provided to CMA at no additional cost.

RM
pt 3/23/95

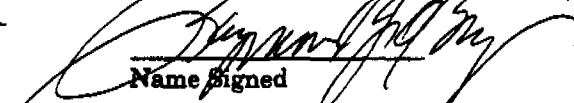
ACCEPTED FOR:

ACCEPTED FOR:

Applied Epidemiology, Inc.

Chemical Manufacturers Association, Inc.


Name Signed


Name Signed

Kenneth A. Mundt, Ph.D.
Name Typed

Raymond J. O'Bryan
Name Typed

President
Title

Controller
Title

March 10, 1995
Date

February 21, 1995
Date

RM*

For purposes of this Agreement, the term "negligence" shall not include acts or omissions that do not materially breach the duty of care applicable to the industry that provides the type of analysis, data programs, and services that are the subject of this Agreement.

Exhibit A

Confidential Information Agreement

This Agreement becomes effective this _____ day of _____ by and between CMA and the Panel Test Sponsors (hereinafter referred to collectively as CMA), and _____ (hereinafter referred to as Contractor).

Whereas, CMA may disclose to Contractor and Contractor may disclose to CMA, certain technical data or information that is commercially valuable and not generally known in its industry of principal use (hereinafter collectively referred to as "Confidential Information") pursuant to Contractor's performance of certain research (CMA Reference No. _____); and,

Whereas, CMA and Contractor desire to provide a procedure for the exchange of such Proprietary Information;

Now, therefore, CMA and Contractor here agree as follows:

1. CMA and Contractor agree to use reasonable care to hold in confidence and not disclose any and all Confidential Information disclosed by either party hereunder. CMA and Contractor obligations set forth herein shall be considered satisfied if Contractor and CMA use the same degree of care to protect and avoid disclosure of Confidential Information received hereunder as CMA and Contractor use to protect and avoid disclosure of their own Proprietary Information.
2. Written information exchanged hereunder shall be considered Confidential Information for the purposes of this Agreement only if such information is clearly marked with an appropriate stamp or legend as Confidential Information. Nonwritten information exchanged hereunder shall only be considered Confidential Information, if at the time of such disclosure, the Information being disclosed is identified as confidential and the disclosing party provides the receiving party with a writing which clearly identifies the nature and content of the disclosed information within thirty (30) days after such disclosure.
3. It is understood that the term "Confidential Information" does not include information which:
 - (a) is published or otherwise in the public domain through no fault of the receiving party;
 - (b) prior to disclosure hereunder, can be demonstrated by the receiving party to have been in its possession prior to receipt under this agreement;
 - (c) is properly obtained without restriction from a third party;
 - (d) is independently developed by the receiving party by individuals who have not had either direct or indirect access to such information;

- (e) is disclosed with the written approval of the disclosing party; or
 - (f) is obligated to be produced by order of a court of competent jurisdiction.
4. Notwithstanding the prohibition against nondisclosure set forth herein CMA and Contractor agree that CMA and Contractor may disclose any Confidential Information received hereunder to the United States Government in connection with Contractor's performance of that certain research project identified as CMA Reference Number _____. Contractor and CMA agree to mark any Confidential Information disclosed to the Government with the appropriate restrictive legend in accordance with applicable regulatory designations which may protect confidentiality or trade secrets.
5. The validity, interpretation and effect of this Agreement shall be governed by the laws of the _____.
6. The term of this Agreement shall be 10 years from the date of the final report under this Agreement.

In Witness Whereof, CMA and Contractor have caused this Agreement to be executed by their duly authorized representatives.

Name Signed

Name Signed

Name Typed

Name Typed

Title

Title

Date

Date