**CLINICAL STUDY AGREEMENT**

This Agreement is entered into as of this \_\_\_\_\_ day of \_\_\_\_\_\_\_, 20\_\_ between The University of Texas System, [Branch] with its principal location in \_\_\_\_\_\_\_\_\_ (hereinafter referred to as "INSTITUTION") and Merck & Co., Inc., a New Jersey corporation with its principal place of business in Rahway, New Jersey (hereinafter referred to as "MERCK") upon the following terms and conditions:

**ARTICLE 1.  
SCOPE OF PROJECT, TERM OF STUDY AND RELATED MATTERS.**

1.1. INSTITUTION agrees to conduct a clinical research study entitled "                   ", Protocol No. \_\_\_\_\_\_\_\_\_\_ in accordance with the protocol attached hereto as Exhibit A and incorporated by reference herein.

1.2. The clinical study shall commence on or about the day of \_\_\_\_\_\_\_\_\_, 1993and be completed within \_\_\_\_\_\_ (     ) months from its initiation, unless extended for an additional period by written agreement of the parties. The clinical study may be terminated in accordance with Article 6.

1.3. INSTITUTION agrees to devote its best efforts to perform efficiently the work required hereunder and agrees to perform the clinical study in conformance with the protocol; generally accepted standards of good clinical practice; and all applicable laws, rules and regulations relating to the conduct of the clinical study, particularly such laws, rules and regulations concerning or promulgated by the Food and Drug Administration.

1.4. INSTITUTION shall provide MERCK with written evidence of review and approval of the clinical study and the patient consent form by the applicable Institutional Review Board prior to the initiation of the clinical study and of the Institutional Review Board's continuing review and approval of the clinical study whenever it is reviewed, but at least once per year.

1.5. INSTITUTION shall (i) prepare and maintain complete and accurate study documentation in compliance with good clinical practice standards and applicable Federal, state and local laws, rules and regulations; and (ii) for each patient participating in the study, promptly prepare and submit to MERCK all original case report forms and such other reports as required by the protocol following completion or termination of the clinical study, or as otherwise required pursuant to the protocol. The completed case report forms and the information contained therein shall be the property of MERCK and may be used by MERCK in any manner whatsoever.

1.6. Study documentation (including all case report forms, source documents and all clinical and other information generated as a result of the study) will be promptly and fully disclosed to MERCK by INSTITUTION upon request or as set forth in the protocol, and also shall be made available at INSTITUTION's site upon request for inspection, copying, review and audit at reasonable times by representatives of MERCK, the Food and Drug Administration or any other regulatory agencies. INSTITUTION agrees to promptly take any reasonable steps that are requested by MERCK as a result of an audit to cure deficiencies in the study documentation and case report forms. Study documentation, as defined above and as further delineated in the protocol and Exhibit B, shall be retained in conformance with applicable federal and local regulations and as specified by MERCK.

1.7 INSTITUTION is not and does not use in any capacity the services of any person debarred under subsections 306(A) or 306(B) of the Generic Drug Enforcement Act of 1992 (the "Act") in connection with any of the services performed by INSTITUTION hereunder. INSTITUTION covenants it will not use in any capacity the services of any person debarred under such subsections of the Act and will immediately disclose in writing to MERCK if any person who is performing services hereunder is debarred or if any action, suit, claim, investigation or legal or administrative proceeding is pending or, to the best of INSTITUTION'S knowledge, threatened, relating to the debarment of INSTITUTION or any person performing services hereunder.

**ARTICLE 2.  
PAYMENT TERMS.**

2.1. For and in consideration of the performance by INSTITUTION of its obligations hereunder, MERCK shall pay to INSTITUTION \_\_\_\_\_ dollars ($      ) per satisfactorily completed patient, up to a maximum of dollars \_\_\_\_\_\_\_\_ ($       ) (the "Grant"), for completion of all patients, based on patients completing the study. [For antibiotic trials, Section 2.1 is replaced with the following: "For and in consideration of the performance by INSTITUTION of its obligations hereunder, MERCK shall pay to the INSTITUTION\_\_\_\_\_\_dollars ($\_\_\_\_\_\_\_) per satisfactorily completed fully evaluable patient, up to a maximum of \_\_\_\_\_\_\_dollars ($\_\_\_\_\_\_\_) (the "Grant"), for completion of \_\_\_\_\_fully evaluable patients".]

2.2. The Grant shall be due and payable in accordance with the schedule set forth in Exhibit C.

2.3. Amounts due and owing hereunder shall be adjusted as follows:

(i) Payments will not be made for costs resulting from the enrollment of patients who upon entering the study violate protocol inclusionary or exclusionary criteria, unless agreed to in writing by the MERCK clinical monitor;

(ii) If patients are enrolled for less than the specified length of time for completion of the study, payments will be made for such patients based on the costs per patient as set forth in the budget attached hereto as Exhibit D; [For antibiotic trials, (ii) is replaced with the following: "If patients are enrolled for less than the specified length of time for completion of the study when terminated due to an adverse experience, payments will be made for such patients based on the costs per patient as set forth in the budget attached hereto as Exhibit D;] and

(iii) Payments shall be made for the number of patients who successfully complete the study in accordance with this Agreement and the protocol, and for which case report forms are submitted in accordance with Section 1.5.

2.4. INSTITUTION acknowledges that it has included all its direct and indirect costs for the clinical study in the approved budget attached hereto as Exhibit D and in no event shall the Grant exceed the total sum of dollars \_\_\_\_\_\_\_ ($         ) without written authorization from MERCK.

2.5. Payments shall be made payable to \_\_\_\_\_\_\_\_\_\_ and forwarded to the following address:

[Name of Institution]  
[Address]  
Attention:  
[Federal Tax I.D. No. or Social Security No.:]

**ARTICLE 3.  
PRINCIPAL INVESTIGATOR.**

The Principal Investigator for this clinical study shall be Dr. \_\_\_\_\_\_\_\_\_\_ . INSTITUTION agrees to promptly inform MERCK of any event or condition adversely affecting the satisfactory completion of the clinical study by the Principal Investigator. In the event the Principal Investigator shall be unable to complete this clinical study and INSTITUTION and MERCK shall be unable to mutually agree to a substitute investigator within a period of fifteen (15) days, this Agreement shall be automatically terminated at the discretion of MERCK.

**ARTICLE 4.  
PUBLICATION.**

**[Long Form Alternative - Collaborative Publications/Multi-Center Studies]\***

It is understood that this study is part of a multi-center trial and INSTITUTION will be free to publish the results of its part of the study in collaboration with the other investigators in this trial, but with due regard to MERCK's confidential information and materials. Subsequent to the multi-center publication or twenty-four (24) months after completion of the study, whichever occurs first, INSTITUTION may itself publish the results of the study, with due regard to MERCK's confidential information. In either case, INSTITUTION agrees to submit a copy of any manuscript and/or abstract to MERCK for review and comment sixty (60) days prior to its submission for publication. MERCK shall have the applicable sixty (60) day period to respond to INSTITUTION with any requested revisions. INSTITUTION agrees to delete any confidential information identified by MERCK prior to submitting such manuscript and/or abstract for publication. If reasonably requested by INSTITUTION, MERCK will take reasonable steps to expedite the review time to less than the applicable sixty (60) day period to meet INSTITUTION's publication deadlines. Upon notification by MERCK that such expedited review has been completed, INSTITUTION may submit the manuscript and/or abstract for publication after deleting any confidential information identified by MERCK. MERCK also has the right to publish the results of this study. If MERCK so publishes, MERCK personnel will consult with the participating investigators prior to the submission of the manuscript and/or abstract for publication and thereafter is free to publish the results of the study.

**[Alternative - Non-Collaborative Publications Not Involving Multi-Center Studies]\***

INSTITUTION shall have the right to publish the results of its part of the study either independently or in collaboration with MERCK. In either case, INSTITUTION agrees to submit a copy of any manuscript and/or abstract to MERCK for review and comment sixty (60) days prior to its submission for publication. MERCK shall have the applicable sixty (60) day period to respond to INSTITUTION with any requested revisions. INSTITUTION agrees to delete any confidential information identified by MERCK prior to submitting such manuscript and/or abstract for publication. If reasonably requested by INSTITUTION, MERCK will take reasonable steps to expedite the review process to less than the sixty (60) day period to meet INSTITUTION's publication deadlines. Upon notification by MERCK that such expedited review has been completed, INSTITUTION may submit the manuscript and/or abstract for publication after deleting any confidential information identified by MERCK. MERCK also has the right to publish the results of this study. If MERCK so publishes, MERCK personnel will consult with participating investigators prior to the submission of the manuscript and/or abstract for publication and thereafter is free to publish the results of the study.

**ARTICLE 5.  
CONFIDENTIALITY.**

5.1. INSTITUTION agrees not to disclose to any third party any information disclosed to it under this Agreement and identified by MERCK as confidential for a period of five (5) years from the date of disclosure or from the termination date of this study, whichever is later, except INSTITUTION may disclose information to staff members, employees or medical students necessary for the conduct of the study and who are bound by similar written obligations of confidentiality. This non-disclosure obligation shall not apply to:

(i) information that is in the public domain or subsequently enters the public domain through no fault of INSTITUTION;

(ii) information that is presently known or becomes known to INSTITUTION from its own independent sources from a person having the legal right to disclose information;

(iii) information that INSTITUTION receives from any third party not under a confidential obligation to keep such information confidential; or

(iv) information that is required to be disclosed by law.

INSTITUTION acknowledges that all information relating to this study, including, but not limited to, the protocol and the Confidential Investigator Brochure is confidential. If INSTITUTION is required to disclose confidential information pursuant to Sections 5.1.(iv), the INSTITUTION shall notify MERCK, and the INSTITUTION and MERCK shall agree to a mutually satisfactory way to disclose such information as necessary and in accordance with applicable law.

5.2. Notwithstanding anything to the contrary in Section 5.1., with respect to research subjects' medical records, the parties agree to hold in confidence the identity of the patients in accordance with all applicable Federal or local laws, rules and regulations.

5.3. INSTITUTION agrees not to use any subject diagnosis, tests, bodily fluid, tissue biopsies, and/or other materials collected in the course of conducting the study, for or in support of any commercial development or uses unless agreed to otherwise in writing by MERCK.

**ARTICLE 6.  
TERMINATION.**

6.1. Any party may terminate this study or the enrollment of patients into this study for any reason upon thirty (30) days written notice to the other party. Upon receipt of the termination notice, the INSTITUTION shall immediately cease enrollment of patients into the study, and within thirty (30) days from receipt of such notice, shall terminate the study with respect to the enrolled patients. Such termination shall be in an orderly and prompt manner and pursuant to consultations with the MERCK monitor.

6.2. Upon termination of the study, INSTITUTION shall deliver to MERCK within sixty (60) days from the receipt of the termination notice all completed case report forms and all unused drug supplies.

6.3. In the event of termination, the sum for professional services and expenses payable under this Agreement shall be limited to the pro-rated fees based on actual work performed and actual non-cancelable expenses committed pursuant to the protocol, except in the event of termination by INSTITUTION for convenience only and not relating to patient safety, the sum for professional services and expenses payable under this Agreement shall be limited to the pro-rated fees based on actual work performed. If at the date of termination of the study, the total amount that MERCK has paid to INSTITUTION exceeds the amount to which INSTITUTION is entitled, INSTITUTION shall return the difference to MERCK within sixty (60) days from the termination date. If at the date of termination of the study, the total amount that MERCK has paid INSTITUTION is less than the amount to which INSTITUTION is entitled, INSTITUTION shall submit a statement to MERCK for the difference within sixty (60) days from the termination date. MERCK shall pay the approved amount of INSTITUTION's request within sixty (60) days after receiving INSTITUTION's statement and all documentation required to be submitted by INSTITUTION pursuant to Section 1.6. In no event shall the amount owed under this Agreement exceed the amount of the Grant set forth in Section 2.1.

6.4. Termination of this Agreement by either party shall not affect the rights and obligations of the parties accrued prior to the effective date of the termination. The rights and duties under Articles 1, 4, 5, 7 and 8 survive the termination or expiration of this Agreement.

**ARTICLE 7.  
PATENTS AND INVENTIONS**

It is recognized and understood that the existing inventions and technologies of MERCK or INSTITUTION are their separate property, respectively, and are not affected by this Agreement (including, but not limited to, the MERCK study drug, and information and technology relating to the protocol) and neither party shall have any claims to or rights in such existing inventions and technologies of the other party. Title to any inventions or discoveries conceived and reduced to practice solely by INSTITUTION employees arising from this study shall be owned by the INSTITUTION and shall be promptly disclosed in writing to MERCK. Title to any inventions or discoveries conceived and reduced to practice jointly by MERCK and INSTITUTION employees arising from this study shall be jointly owned by MERCK and INSTITUTION. The INSTITUTION, consistent with the INSTITUTION's patent policy, will offer MERCK the first opportunity to enter into a royalty-bearing license for INSTITUTION's rights in such invention or discovery. Such license shall be exclusive and worldwide to the maximum extent permitted by the established policy of INSTITUTION with a reasonable royalty and will provide MERCK with an exclusive right to make, have made, use and sell such invention or discovery and the right to sublicense such rights. Except as otherwise stated herein, any and all inventions and discoveries arising from this study are the sole and exclusive property of MERCK.

**ARTICLE 8.  
INDEMNIFICATION.**

MERCK agrees to indemnify INSTITUTION upon the terms and conditions set forth in Exhibit E attached hereto and incorporated by reference herein.

**ARTICLE 9.  
ASSIGNMENT AND SUBCONTRACTING.**

Neither this Agreement nor the rights or obligations hereunder shall be assignable or otherwise transferred or subcontracted by INSTITUTION without MERCK's prior written consent.

**ARTICLE 10.  
INDEPENDENT CONTRACTOR.**

In undertaking to perform this research study for MERCK, it is understood that INSTITUTION is doing so as an independent contractor and not as an employee of MERCK.

**ARTICLE 11.  
GOVERNING LAW.**

This Agreement shall be governed by and construed in accordance with the laws of the state of the principal location of the INSTITUTION set forth in the first page to this Agreement.

**ARTICLE 12.  
NOTICES.**

All notices of other communications which are required or permitted hereunder shall be in writing and sufficient if delivered personally, sent by prepaid air courier, sent by mail or sent by telefax transmission, addressed as follows:

if to INSTITUTION, to:

[Name of Institution]  
[Address]  
Attention:  
Phone No.:  
Fax No.:

if to PRINCIPAL INVESTIGATOR, to:

[Name]  
[Address]; and  
Phone No.:  
Fax No.:

if to MERCK, to:

Merck & Co., Inc.  
[address]  
Attention: [Name of Clinical Monitor]  
Phone No.:  
Fax No.:

Any such communication shall be deemed to have been given when delivered if personally delivered, on the business day after dispatch if sent by air courier, on the third business day following the date of mailing if sent by mail and on the date of telefax if sent by telefax transmission or electronic mail.

**ARTICLE 13.  
ENTIRE AGREEMENT.**

This Agreement constitutes the entire agreement between the parties relating to the clinical study and supersedes all prior negotiations, representations, agreements, and understandings among the parties with respect thereto. The parties will attempt to read the Agreement and the protocol consistently and in the event a section of this Agreement and a section in the protocol address the same issue and a specific term in the protocol's section conflicts with a specific term in the Agreement's section, both sections will be given effect with only the specific term in this Agreement controlling with respect to the specific conflicting term in the protocol.

**ARTICLE 14.  
AMENDMENT, MODIFICATION AND WAIVER.**

This Agreement shall not be altered or otherwise amended except pursuant to an instrument in writing signed by each of the parties hereto, except that any party to this Agreement may waive any obligation owed to it by another party under this Agreement. The waiver by any party hereto of a breach of any provision of this Agreement shall not operate or be construed as a waiver of any subsequent breach.

IN WITNESS WHEREOF, the parties have caused this Agreement to be duly executed by an appropriate officer as of the day and year first above written.

|  |  |
| --- | --- |
| The University of Texas \_\_\_\_\_\_\_\_\_\_\_\_\_\_  By: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_                                 Name  Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | Merck & Co., Inc.  By: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_                                 Name  Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

I have read this Agreement and understand  
my obligations hereunder.

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

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

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  
ENDNOTES**

\* Include one alternative and delete other alternative.

**EXHIBITS**

|  |  |
| --- | --- |
| Exhibit A - | Protocol |
| Exhibit B - | Study Documentation |
| Exhibit C - | Schedule of Payments |
| Exhibit D - | Budget |
| Exhibit E - | Indemnification Terms |

**EXHIBIT A**

**PROTOCOL**

**EXHIBIT B**

Study Documentation includes copies of all case report forms, data correction forms, workbooks, source documents, monitoring logs and appointment schedules, sponsor-investigator correspondence and regulatory documents (e.g., signed protocol and amendments, ethics or Institutional Review Committee correspondence and approval, signed and approved patient consent forms, statement of investigator, clinical supplies receipts and distribution records).

Source documents include all original observations or notations of clinical activities and all reports and records necessary for the evaluation and reconstruction of the clinical research study. Accordingly, source documents include all laboratory reports, ECG tracings, X-rays, radiologist reports, biopsy reports, ultrasound photographs, patient progress notes, hospital charts or pharmacy records and any other similar reports or records of any procedure performed in accordance with the protocol. Source documentation may also include workbooks when information is recorded directly onto such forms. In the event that the workbook is used as a source document by a physician not identified as a primary or secondary investigator in the protocol (e.g., ophthalmologist) or not under the direct supervision of the primary investigator, the workbook must be signed and dated by the individual making the entry.

**EXHIBIT C**

Samples of alternative payment schedules are attached. The payment schedule to be attached as Exhibit C to the executed Agreement for the site is to be based on clinical endpoints/milestones in accordance with department practice and procedure. A given payment schedule may combine provisions from the attached sample schedules, provide for more or less than the number of payments in the attached sample schedules or be based on other clinical endpoints/milestones, as appropriate.

**ALTERNATIVE 1  
[Sample Based on Clinical Endpoints in the Training and Reference Manual for Clinical Monitors]**

**EXHIBIT C**

The Grant shall be due and payable as follows:

1st Payment: $        (or \_\_\_\_\_% of the total Grant) upon initiation of the study.

2nd Payment: $        (or \_\_\_\_\_% of the total Grant) when the th patient has been entered into the study.\*

3rd Payment: $        (or \_\_\_\_\_% of the total Grant) when patients have completed the study and case report forms therefore have been satisfactorily completed and submitted to MERCK.\*

4th Payment: $        (or \_\_\_\_\_% of the total Grant) upon receipt by MERCK of all satisfactorily completed case report forms (including satisfactory resolution of all data inquiries and deficiencies therein).\*

Amounts will be adjusted, and payments will not be made, for unsatisfactory case report forms or for patients with unresolved data deficiencies in the study documentation.

\*Upon receipt by MERCK of paperwork satisfactorily evidencing that the amount is due and payable as reasonably determined by MERCK and the principal investigator, a check for the applicable amount is generally issued by MERCK within 60 days.

**ALTERNATIVE 2  
[Sample Suitable for to Vaccine Studies]**

**EXHIBIT C**

The following schedule is based on the assumption that enrollment will be completed within a month period and may be revised at the discretion of MERCK if the enrollment is not completed with a month period:

The Grant shall be due and payable as follows:

1st Payment: $        (or \_\_\_\_\_% of the total Grant) upon initiation of the study.

2nd Payment: $         (or \_\_\_\_\_% of the total Grant) when all first injections are completed.\*

3rd Payment: $        (or \_\_\_\_\_% of the total Grant) when all additional injections required by the protocol and clinical and serologic follow-up are completed.\*

4th Payment: $        (or \_\_\_\_\_% of the total Grant) upon receipt by MERCK of all satisfactorily completed case report forms (including satisfactory resolution of all data inquiries and deficiencies therein).\*

Amounts will be adjusted, and payments will not be made, for unsatisfactory case report forms or for patients with unresolved data deficiencies in the study documentation.

\*Upon receipt by MERCK of paperwork satisfactorily evidencing that the amount is due and payable as reasonably determined by MERCK and the principal investigator, a check for the applicable amount is generally issued by MERCK within 60 days.

**ALTERNATIVE 3  
[Sample Suitable for Study Extensions]**

**EXHIBIT C**

The Grant shall be due and payable as follows:

1st Payment: $        (or \_\_\_\_\_% of the total Grant) upon initiation of the study.

2nd Payment: $        (or \_\_\_\_\_% of the total Grant) when all patients complete the six week extension.\*

3rd Payment: $        (or \_\_\_\_\_% of the total Grant) when all patients complete the twelve-week extension.\*

4th Payment: $        (or \_\_\_\_\_% of the total Grant) upon receipt by MERCK of all satisfactorily completed case report forms.\*

5th Payment: $        (or \_\_\_\_\_% of the total Grant) upon satisfactory resolution of all data inquiries and deficiencies.\*

Amounts will be adjusted, and payments will not be made, for unsatisfactory case report forms or for patients with unresolved data deficiencies in the study documentation.

\*Upon receipt by MERCK of paperwork satisfactorily evidencing that the amount is due and payable as reasonably determined by MERCK and the principal investigator, a check for the applicable amount is generally issued by MERCK within 60 days.

**ALTERNATIVE 4  
[Sample Suitable for Antibiotic Studies]**

**EXHIBIT C**

Reimbursement for participation in the study is based on the following:

$      per fully evaluable patient, including both clinical and microbiological documentation of infection.

$      per patient lacking only microbiological documentation of infection, but otherwise evaluable.

The payments shall be due and payable as follows:

1st Payment: $        (or \_\_\_\_\_% of the total Grant) upon initiation of the study.

2nd Payment: $        (or \_\_\_\_\_% of the total Grant) will be made when the th patient has been enrolled into the study and after MERCK has received satisfactorily completed typed case report forms for the first patients.\*

3rd Payment: $        (or \_\_\_\_\_% of the total Grant) will be made when the Principal Investigator has completed patient enrollment; such amount may be increased depending on pace of enrollment, percentage of evaluable patients, quality of case report form data, and total enrollment objectives at the time as determined by MERCK at its sole discretion.\*

4th Payment: The final payment will be adjusted according to the actual number of patients who complete the study, and it will be made when all patients have completed the study and MERCK has received all satisfactorily completed case report forms (including satisfactory resolution of all data inquiries and deficiencies therein). In no event will the amount of the total three payments plus the amount of the fourth payment be more than the actual amount of the Grant.\*

Amounts will be adjusted, and payments will not be made, for unsatisfactory case report forms or for patients with unresolved data deficiencies in the study documentation.

\*Upon receipt by MERCK of paperwork satisfactorily evidencing that the amount is due and payable as reasonably determined by MERCK and the principal investigator, a check for the applicable amount is generally issued by MERCK within 60 days.

[This budget may be revised to reflect the practice in the department.]

**EXHIBIT D  
BUDGET**

|  |  |  |  |
| --- | --- | --- | --- |
| BUDGET ITEM: | UNIT COST($) | NUMBER REQUIRED  BY PROTOCOL | PER PATIENT COST($) |

RECRUITMENT /SCREENING:

1.  
2.  
3.  
etc.

PROTOCOL REQUIREMENTS:  
    BASELINE PERIOD:

1.  
2.  
3.  
etc.

    TREATMENT PERIOD:

1.  
2.  
3.  
etc.

    FOLLOW-UP PERIOD:

1.  
2.  
3.  
etc.

    OTHER COSTS:

1.  
2.  
3.  
etc.

    EQUIPMENT:

1.  
2.  
3.  
etc.

STUDY SITE PERSONNEL:

    [Include Title/Position and Function/Basis for Payment]

INSTITUTIONAL OVERHEAD (      %), IF REQUIRED, FOR PERSONNEL COST ONLY:         \_\_\_\_\_\_\_\_\_\_\_

                                                                                                                   PER PATIENT TOTAL:    \_\_\_\_\_\_\_\_\_\_\_

NUMBER OF PATIENTS REQUIRED BY PROTOCOL: \_\_\_\_\_\_\_\_\_

                                                                                                                   TOTAL BUDGET:            \_\_\_\_\_\_\_\_\_\_\_

**EXHIBIT E  
INDEMNIFICATION TERMS**

INSTITUTION shall, to the extent authorized under the constitution and laws of the state of Texas, hold MERCK harmless from liability resulting from the negligent acts or omissions of INSTITUTION, its agents or employees pertaining to the activities to be carried out pursuant to the obligations of this Agreement; provided, however, that INSTITUTION shall not hold MERCK harmless from claims arising out of the negligence of MERCK, its officers, agents, or any person or entity not subject to INSTITUTION supervision or control.

MERCK shall indemnify and hold harmless The University of Texas System, INSTITUTION, their regents, officers, agents, and employees from any liability or loss resulting from judgements or claims against them caused by: (i) administration pursuant to the protocol of a medication or drug supplied by or required by SPONSOR; (ii) the proper performance of any procedure called for by and administered pursuant to the protocol; or (iii) the use by SPONSOR of the results of the study; provided, however, that this indemnification does not cover liabilities resulting from a negligent or wrongful act, failure to act or willful malfeasance on the part of any indemnified party.

MERCK'S indemnification policy is subject to the following conditions:

1. compliance by all indemnified parties with applicable federal, state, and local laws and regulations, and strict administration of the drug in accordance with the approved protocol of the study and the written recommendations, suggestions, and pertinent literature provided by MERCK;

2. proper maintenance and availability to MERCK of records concerning the receipt, storage, handling, and administration of the study drug;

3. prompt reporting to MERCK of any significant or alarming developments that may occur during the study;

4. prompt notification to MERCK of any claim and subject to the statutory duty of the Texas Attorney General, authorization to allow MERCK to assume the defense of any such claim, including, without limitation, the right to select defense counsel and the right to settle any claims or suits at its discretion; and

5. subject to the statutory duty of the Texas Attorney General, full cooperation by the indemnified parties with MERCK in defense of any claim.

In addition, if a patient suffers an adverse drug experience resulting directly from administration of the MERCK study drug or the control drug, MERCK will provide reimbursement for the reasonable costs of medical treatment to the extent such costs are not covered by the patient's medical or hospital insurance or by third party or governmental programs providing such coverage.

Revised 6/15/95