**MASTER CLINICAL TRIAL RESEARCH AGREEMENT**

This Agreement is entered into as of July 1, 2004 (“Effective Date”), by and between INTEGRATED THERAPEUTICS GROUP, INC, a wholly owned subsidiary of Schering-Plough Corporation with its office and place of business at 2000 Galloping Hill Road, Kenilworth, New Jersey 07033, hereinafter called ("ITGI") and all of the following (and as further described in Exhibit C) component institutions of THE UNIVERSITY OF TEXAS SYSTEM ("System") located at 201 West 7th Street, Austin, Texas 78701, that is governed by its Board of Regents (“Board”): THE UNIVERSITY OF TEXAS HEALTH CENTER AT TYLER, THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT HOUSTON, THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT SAN ANTONIO, THE UNIVERSITY OF TEXAS M.D. ANDERSON CANCER CENTER, THE UNIVERSITY OF TEXAS MEDICAL BRANCH AT GALVESTON, AND THE UNIVERSITY OF TEXAS SOUTHWESTERN MEDICAL CENTER AT DALLAS (hereinafter collectively referred to as Institution).

The agreement to perform a given Study (as defined below) shall be evidenced by the execution of an Addendum to this Agreement, by or on behalf of ITGI, the particular Institution that is a component of the System, and the Principal Investigator (as defined below), in the form set forth in Exhibit A.

ITGI desires Institution to study the safety and/or efficacy of the compound/drug set forth in Exhibit A and incorporated into this Agreement by reference (the "Study Drug") and Institution is willing to perform certain clinical trial research (the "Study"). The parties hereto agree as follows:

1. **Scope of Work**

The Study to be performed under this Agreement shall be performed in accordance with the terms of the final protocol, including as it may be amended in accordance with the terms of this Agreement, for the Study entitled as set forth in Exhibit A and incorporated into this Agreement by reference (the "Protocol") which is attached as Exhibit B and incorporated into this Agreement by reference. Institution certifies that, to its best knowledge, its facilities and population are adequate to perform the Study contemplated by this Agreement and the Protocol. Institution agrees and Principal Investigator acknowledges (named in Article 2 below) that all aspects of the Study will be conducted in conformity with all applicable federal, state, local laws, regulations and the principles of good clinical practice as laid down by the International Conference on Harmonization (“ICH”) topic E6 for Guidance on Good Clinical Practice CPMP/ICH/135/95 (hereinafter referred to as “GCP”). Institution further agrees not to conduct any research activities with the Study Drug which are contrary to the provisions of the Protocol or outside the scope of the Protocol. Institution will undertake the Study as the legal sponsor of the Protocol and will fulfill the requisite sponsor duties and obligations in conducting the Study. The parties understand and agree that if ITGI elects to utilize a Contract Research Organization (“CRO”) as its representative agent, then the terms and conditions of this Agreement shall still apply.

2. **Principal Investigator**

Institution's principal investigator is as set forth in Exhibit A and incorporated into this Agreement by reference, who with any sub-investigators shall be collectively referred to as "Principal Investigator". Principal Investigator will be responsible for the direction and supervision of all Study efforts in accordance with applicable Institution policies, the Protocol and this Agreement. In the event that the Principal Investigator who signs either the Protocol and/or this Agreement leaves or is removed from the Institution, then Institution shall, within ten (10) days of such departure by Principal Investigator, provide written notice of such event to ITGI. Any successor to Principal Investigator shall be required to abide with all the terms and conditions of the Protocol and this Agreement and to sign each such document as evidence of such obligation (although failure to so sign will not relieve such successor from abiding with all the terms and conditions of the Protocol and this Agreement).

Institution represents and warrants that it will not use in any capacity, in connection with any services to be performed under this Agreement, any individual who has been debarred pursuant to the Federal Food, Drug and Cosmetic Act or excluded from a federal health care program.

3. **Inspection Rights**

It is agreed that ITGI and others designated by ITGI may, at mutually agreeable times prior to Study initiation, during the Study and for a reasonable time after completion or early termination of the Study, arrange with Principal Investigator or his/her designee:

(i) to examine and inspect, during regular business hours, qualifications of the staff and Institution facilities required for performance of the Study according to GCP requirements; and

(ii) subject to applicable patient confidentiality considerations, to inspect, audit, and to copy or have copied, all data and work product relating to the Study conducted under this Agreement and to inspect and make copies of all data necessary for ITGI (Institution will be reimbursed for reasonable cost of copies) to confirm that the Study is being conducted in conformance with the Protocol and in compliance with all applicable legal and regulatory requirements, including without limitation, any applicable requirements of the United States Food and Drug Administration ("FDA") provided that personally identifiable patient medical records will not be copied except with the appropriate patient authorization or other approval.

4. **Clinical Trial Approvals**

A. Institution shall be responsible for obtaining the following:

(i) approval of the Protocol, any informed consent relating to the Study and advertisement, if any, pertaining to the enrollment of subjects in the Study by the appropriate Institutional Review Board ("IRB") prior to beginning any Study on human subjects;

(ii) an informed consent which complies with all applicable federal, state, and local laws and regulations signed by or on behalf of each human subject prior to the subject's participating in the Study; and

(iii) an IRB approved Heath Insurance Portability and Accountability Act of 1996 authorization to use and disclose personal health information (either incorporated into the informed consent form or in a separate document) giving ITGI and its representatives access and use of a subject’s health information as contemplated under this Agreement and Protocol which complies with all applicable federal, state, and local laws and regulations signed by or on behalf of each human subject prior to the subject's participating in the Study.

B. In the event the Institution’s IRB requires changes in the Protocol or informed consent, ITGI shall be advised in advance and all modifications to the Protocol and informed consent must be approved in advance by ITGI. Institution and Principal Investigator shall not modify the Study described in the Protocol once finalized and after approval by the IRB without the prior written approval of ITGI.

C. The Principal Investigator and Institution shall ensure that IRB approval shall be maintained current at all times and in the event that the Study continues beyond the period of the initial IRB approval, shall ensure that appropriate periodic IRB re-approval is obtained without lapse in approval status.

5. **Term of Agreement**

A. It is anticipated that the Study shall begin upon the execution of the Addenda set forth in Exhibit A and incorporated into this Agreement by reference, and shall continue until the Study is completed and all final Study documentation required to be provided under the Protocol is received and accepted by ITGI. If at any time Institution or Principal Investigator have reason to believe that the Study will not be initiated or completed as per the schedule initially anticipated and agreed upon by the parties, ITGI will be advised, in writing, of the reason(s) and length of additional time required to commence or complete work, and this Agreement may be terminated by ITGI as provided in Article 6.

B. The term of this Agreement begins as of the Effective Date and will be in effect for five (5) years unless terminated by either party upon sixty (60) days written notice to the other, except for any Study then in progress. If a Study is in progress at the time of any attempted termination pursuant to this Article 5B, then the terms and conditions of this Agreement shall be considered to be in effect until such time as the Study has been completed or, in the alternative, terminated pursuant to Article 6 of this Agreement.

6. **Termination and Enrollment Cap**

A. Either party may terminate Institution’s participation in any Study pursuant to this Agreement by giving thirty (30) days written notice to the other party. In the event thirty (30) days is reasonably determined by Institution to be insufficient notice based upon evaluation of risks to enrolled research subject(s) then receiving the Study Drug, the parties will cooperate to safely withdraw subjects from Study over a mutually agreeable period of time but in no event shall ITGI's obligation to supply Study Drug hereunder extend beyond a reasonable period. Notwithstanding the foregoing, in the event ITGI believes that immediate termination is necessary due to its evaluation of risks to enrolled Study subject(s), ITGI may terminate this Agreement immediately.

B. Notwithstanding any other provision hereof, ITGI shall be entitled to terminate this Agreement for any Material Breach which shall be defined as:

(i) Institution's failure to comply with its material obligations, responsibilities and the material terms and conditions of this Agreement and the Protocol;

C. In the event of termination:

(i) Institution shall return to ITGI, or its designee, all unused materials, including but not limited to, Study Drug and clinical supplies (unless written authorization to retain or destroy them is given by ITGI in which case Institution shall comply with the applicable provisions of Article 11 hereof);

(ii) except in the event of termination because of a Material Breach by Institution, and unless otherwise specified in writing between the parties, the total sums payable by ITGI pursuant to this Agreement shall be equitably pro-rated for actual work performed in accordance with the Protocol to date of notice of termination with any unearned portion of funds previously paid by ITGI to Institution being refunded to ITGI;

(iii) in the event of termination as a result of a Material Breach, the parties agree to make a good faith effort to reach agreement to compensate Institution for actual work performed in accordance with the Protocol to date of notice of termination; and

(iv) Principal Investigator shall return to ITGI all Confidential Information (as defined in Article 9 hereof) owned or controlled by ITGI and in the possession of Institution.

D. The termination of this Agreement shall not relieve either party of its obligation to the other in respect of:

(i) retaining in confidence all Confidential Information (as defined in Article 9 hereof);

(ii) complying with record keeping and reporting obligations (under Article 7 hereof);

(iii) obtaining review of any publications (under Article 10 hereof) and approval of publicity and promotional statements (under Article 17 hereof);

(iv) compensation for services performed to date of notice of termination, except as set forth in Article 6.C(iii) hereof;

(v) complying with obligations relating to clinical supplies (under Article 11 hereof);

(vi) indemnification and insurance obligations (under Article 12 hereof);

(vii) inspection rights (under Article 3 hereof); and

(viii) obligation to assist in obtaining patent protection (under Article 13 hereof)

all of which obligations are binding on the appropriate party and shall remain in full force and effect as set forth in this Agreement.

E. ITGI reserves the right to limit enrollment by giving written notice, or by giving notice by telephone followed by written notice, to Institution and Principal Investigator to cease further enrollment in the Study ("Enrollment Cap"). Upon receipt of such notice, Institution agrees to and Principal Investigator shall enroll no further patients in the Study. Unless otherwise specified in writing between the parties, in the event of such a notice to cease further enrollment, the total sums payable by ITGI pursuant to this Agreement shall be equitably pro-rated for the number of patients enrolled to the date of such notice, with any funds for patients beyond the Enrollment Cap previously paid by ITGI to Institution being refunded to ITGI.

7. **Records and Reports**

A. Principal Investigator and/or Institution shall have the following record keeping and reporting obligations:

(i) preparation and maintenance of complete, accurately written records, accounts, notes, reports Study files and data (Case Report Forms/Electronic Data Capture) relating to the Study under this Agreement; and

(ii) conduct the Study and maintain records and data during and after the term or early termination of this Agreement in compliance with all applicable legal and regulatory requirements, including without limitation, any applicable requirements of the FDA.

(iii) Preparation and submission of periodic progress reports as reasonably requested by ITGI which will include the following (but is not limited to):

(a) Enrollment summaries,

(b) Enrollment forecasting for Study Drug supply management,

(c) Final Study report or acceptable equivalent according to specified content within a reasonable time after completion of the Study but in no event longer than three (3) months after completion of the Study.

B. Principal Investigator and/or Institution shall notify ITGI within twenty-four (24) hours after learning of any serious and/or unexpected adverse drug reaction affecting any patient in the Study. Institution further agrees to follow up such notification of adverse drug reaction with appropriate reports in compliance with the Protocol and all applicable legal and regulatory requirements.

C. Principal Investigator and Institution shall notify Sponsor of any Quality Complaints associated with the Study Drug provided under this Agreement, should they become aware of any within twenty-four (24) hours after learning of such event. A Study Drug Quality Complaint is defined as information concerning any bacteriological contamination or significant chemical or physical change or deterioration in the Study Drug (e.g. adulteration, contamination, tampering, misbranding, lack of sterility, or lack of stability). It also includes any other complaint related to the identity, strength, quality or purity of the Study Drug or other Study Drug defect. Principal Investigator and Institution shall follow up such notification with reasonably requested information about the Study Drug Quality Complaint.

D. Institution further agrees to conduct the Study and maintain records and data during and after the term or early termination of this Agreement in compliance with all applicable legal and regulatory requirements, including without limitation, any applicable requirements of the FDA. Institution further agrees to permit ITGI or ITGI's representatives to examine and audit all records and reports, with prior written notification from ITGI and during normal business hours (subject to applicable patient confidentiality considerations).

E. Institution agrees to notify ITGI promptly or at most within three (3) regular business days in the event that the FDA or any other regulatory authority notifies the Study site of a pending inspection/audit. In addition, Institution will promptly forward to ITGI any written communication received as a result of the inspection/audit and agrees to allow ITGI to assist in responding to any citations. Such responses shall be made within two (2) weeks of issuance of any citations or within any earlier deadline set by the issuing regulatory authority. Institution shall also provide to ITGI copies of any documents provided to any inspector or auditor.

8. **Cost and Payment**

The budget for the Study which is attached as Exhibit B and which will be signed by both the Institution and ITGI which shall be deemed to be incorporated by reference into this Agreement (“Budget”). The payment(s) set forth in such Budget are acknowledged by the parties hereto to be adequate consideration for the work undertaken hereunder. In the event that ITGI is not providing funding for the Study then a Budget will not be entered into between Institution and ITGI. Further, any terms concerning funding in this Agreement would then not apply to that particular Study.

9. **Confidential Information**

A. The Confidentiality Period will be either five (5) years from the termination of the specific Study as set forth in the addendum or a longer period of time mutually agreed upon by ITGI and Institution (“Confidentiality Period”). Institution will reasonably consider lengthening the five (5) year Confidentiality Period for Phase I and Phase II Studies. The agreed upon Confidentiality Period will be set forth in the Addendum contained in Exhibit “A”. Subject to Institution’s right to publish results under Article 10, during and for the Confidentiality Period after the term or early termination of the particular Study addendum to this Agreement, Institution shall retain in confidence all test articles and proprietary data and/or information obtained from ITGI or generated pursuant to the particular Study including, but not limited to, the Protocol, the investigator's brochure, interim results and any other information or material disclosed under secrecy agreements previously entered into between the parties ("Confidential Information"). This restriction shall not apply to Confidential Information:

(i) which is or becomes public knowledge (through no fault of Institution or Principal Investigator);

(ii) which is lawfully made available to Institution by an independent third party owing no obligation of confidentiality to ITGI with regard thereto (and such lawful right can be properly demonstrated by Institution or Principal Investigator);

(iii) which is already in Institution's possession at the time of receipt from ITGI or is independently developed by Institution (and such prior possession or independent development can be properly demonstrated by Institution as evidenced by written records);

(iv) published in accordance with the express terms of this Agreement; or

(v) which is required by law, regulation, rule, act or order of any governmental authority or agency to be disclosed by Institution; or

(vi) is disclosed for the purpose of Study subject informed consent and/or for the safety and well being of a Study subject in connection with medically necessary treatment.

B. To permit ITGI an opportunity to intervene by seeking a protective order or other similar order, in order to limit or prevent disclosures of Confidential Information, Institution shall promptly notify ITGI, in writing, if it is requested by a court order, a governmental agency, or any other entity to disclose Confidential Information in Institution's or Principal Investigator's possession and thereafter Institution or Principal Investigator shall disclose only the minimum Confidential Information required to be disclosed in order to comply, whether or not a protective order or other similar order is obtained by ITGI.

C. Subject to applicable federal, state or local legal and regulatory requirements, Institution agrees to promptly return to ITGI, upon its request, all Confidential Information obtained from ITGI or belonging to ITGI pursuant to this Agreement; provided, however, that Institution may retain one copy of Confidential Information in a secure location for purposes of identifying Institution's obligations under these confidentiality provisions.

D. Institution shall limit disclosure of Confidential Information received hereunder to only those of its representatives, agents, officers and employees (collectively, "Agents") who are directly involved with the Study and only on a need to know basis. Institution shall advise its Agents upon disclosure to them of any Confidential Information of the proprietary nature thereof and the terms and conditions of this Agreement and shall use all reasonable safeguards to prevent unauthorized disclosure by such Agents. Institution shall be responsible for any breach of these confidentiality provisions by its Agents.

10. **Data, Publications and Other Rights**

In recognition of the importance of disseminating information relating to any novel or important observations or results arising from the Study and understanding that such need must be balanced with ITGI's obligations to maintain control over Confidential Information as well as to comply with appropriate rules and regulations of the FDA, the parties hereby agree to the following:

A. Subject to the terms and conditions of this Agreement, Institution and Principal Investigator shall have the right to publish or publicly present the results of the Study. Institution further agrees to provide thirty (30) days written notice to ITGI prior to submission for publication or presentation to permit ITGI to review drafts of abstracts and manuscripts for publication (including slides and texts of oral or other public presentations, collectively or individually a "Public Presentation") which report any results, including without limitation interim results, arising out of the Study. ITGI shall have the right to review and comment on the data analysis and presentation to:

(i) ensure that Confidential Information is protected by the provisions contained in Article 10B below;

(ii) ensure the accuracy of the information contained in the Public Presentation.

If the parties disagree concerning the accuracy and appropriateness of the data analysis and presentation, and/or confidentiality of ITGI's Confidential Information, Institution agrees to meet with ITGI's representatives at the Study site or as otherwise agreed, prior to submission of a Public Presentation, for the purpose of making good faith efforts to discuss and resolve any such issues or disagreement.

B. No Public Presentation shall contain any Confidential Information (except Study results which have been reviewed in accordance with paragraph A of this Article) of ITGI (as defined in Article 9) and shall be confined to new discoveries and interpretations of scientific fact. At ITGI's written request, ITGI shall be acknowledged as one of many or as the sole financial supporter, as the case may be, of the Study reported in the Public Presentation.

C. If ITGI believes there is patentable subject matter contained in any Public Presentation submitted for review, ITGI shall promptly identify such subject matter to Institution. If ITGI requests and at ITGI's expense, Institution shall use reasonable efforts to assist ITGI to file a patent application covering such subject matter with the United States Patent and Trademark Office or through the Patent Cooperation Treaty prior to any publication.

D. Subject to Article 13, ITGI is granted full rights of access (including, without limitation, the right to make copies), during normal business hours, to all research data and results generated in the performance of the Study, and the right to use such data and results for any purpose. Institution agrees not to provide any third party with access to or with the right to use the data or results for any purpose without the written permission of ITGI. Notwithstanding Institution’s publication rights as set forth in this Article, Institution agrees that it will only use the results of the Study, including but not limited to, the results of tests and any raw data and statistical data generated therefrom, for its own internal teaching and research purposes.

11. **Clinical Supplies**

ITGI shall make available sufficient quantities of Study Drug, at no cost to Institution and to be provided free of charge to Study subjects, to carry out the Study, it being understood that Institution and the Principal Investigator shall take responsibility for and reasonable steps to maintain appropriate records and assure appropriate supply, handling, storage, distribution and usage of these materials in accordance with the Protocol and any applicable laws and regulations relating thereto. Clinical supplies may not be used for any other purpose than that stated in the Protocol. All unused materials will be returned to ITGI or desginee by Institution at the conclusion of the Study, or upon earlier termination of this Agreement, unless written authorization to destroy or retain them is given by ITGI. If authorization to destroy unused material is given, Institution shall provide ITGI with documentation of Study D rug accountability and the method of destruction.

12. **Indemnification and Insurance**

A. ITGI shall indemnify, defend and hold harmless Institution, System, their Regents, officers, agents, employees and Principal Investigator (and any named co-investigator) from and against any demands, claims, actions, proceedings or costs of judgments which may be made or instituted against any of them by reason of personal injury (including death) to any person, or damage to property, arising out of or connected with manufacturing defects in the Study Drug and ITGI’s use of the results of the Study.

B. Notwithstanding the foregoing, ITGI shall have no indemnification obligation or liability for loss or damage resulting from:

(i) failure of Institution to adhere to the terms and provisions of the Protocol or agreed amendments thereto or ITGI's written recommendations and instructions relative to the administration and use of any drug substances involved in the Study, including, but not limited to, the Study Drug, any comparative drug and any placebo;

(ii) failure of Institution to comply with any applicable FDA or other governmental or state requirements, law, rules or regulations applicable to the performance of its obligations under this Agreement;

(iii) failure of Institution to render professional service or to conduct the Study in a normal, prudent manner; or

(iv) negligent act or omission or willful malfeasance by Institution, its Regents, officers, agents or employees related to the performance of the Study under this Agreement.

C. A condition of ITGI's indemnity obligation is that, whenever Principal Investigator and/or Institution has information from which it may reasonably conclude an incident of bodily injury or death has occurred, Institution shall as soon as possible under the circumstances give notice to ITGI of all pertinent data surrounding such incident. In addition, Principal Investigator and Institution shall comply with all of their obligations with regard to adverse event reporting procedures as set forth in this Agreement and the Protocol and any appendix or attachment thereto. In the event claim is made or suit is brought, Institution and Principal Investigator shall reasonably assist ITGI and cooperate in the gathering of information with respect to the time, place, and circumstances and will use reasonable efforts to assist ITGI in obtaining the names and addresses of the injured parties and available witnesses. Subject to the statutory duties of the Texas Attorney General, Principal Investigator shall and Institution agrees to cooperate with and to authorize ITGI to carry out sole management and defense of such claim or action. Neither Principal Investigator nor Institution, its Regents, officers, agents or employees shall compromise or settle any claim or action without the prior written approval of ITGI.

D. Institution shall, to the extent authorized under the Constitution and laws of the State of Texas, indemnify and hold ITGI harmless from liability resulting from the negligent acts or omissions of Institution, System, their Regents, officers, 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 ITGI harmless from claims arising out of the negligence or willful malfeasance of ITGI, its officers, agents, or employees, or any person or entity not subject to Institution's supervision or control.

E. Each component of System is self-insured pursuant to The University of Texas System Professional Medical Malpractice Self-Insurance Plan, under the authority of Section 59.01, Texas Education Code. The Institution has and will maintain in force during the term of its agreements with third parties adequate insurance to cover its indemnification obligations.

F. ITGI, as with most major pharmaceutical companies, is largely self-insured for its liability exposures. ITGI's assets are sufficient to cover any contemplated self-insured liability assumed by ITGI under this Agreement.

13. **Inventions and Patents**

A. Institution understands and acknowledges that the Study Drug which is being provided to Institution for the purpose of conducting the Study is the property of ITGI and/or that the pharmaceutical compound may be subject to certain intellectual property rights owned by or licensed to ITGI. This Agreement shall not be deemed or construed to convey or transfer any of such intellectual property rights to Institution except insofar as necessary to permit Institution to conduct the Study which is the subject of this Agreement.

B. ITGI understands and acknowledges that ownership and rights to any new and patentable discovery, unpatentable, technology, technical know-how or other intellectual property arising in the performance of the Protocol and Study shall be governed by the following provisions: Inventions made by the Principal Investigator or other employees of Institution shall be the property of Institution (hereinafter "Institution Inventions"); and Inventions made jointly by employees or agents of ITGI and either the Principal Investigator or other employees of Institution shall be the joint property of ITGI and Institution (hereinafter "Joint Inventions"). Institution will promptly notify ITGI in writing of any such Inventions. If ITGI requests, and at ITGI's sole expense, Institution will file patent applications to any such Institution Inventions, and will provide ITGI with reasonable assistance to obtain patents to any such Joint Inventions including executing any invention documents. Institution and ITGI shall consult and agree upon the patent filing and prosecution strategy for all Joint Inventions.

C. The foregoing notwithstanding, any inventions or discoveries arising out of any unauthorized use or modifications to the Study Drug, whether patentable or not, made by the Principal Investigator or other employees of Institution shall be the property of the ITGI (hereinafter "ITGI Inventions"). Institution will promptly notify ITGI in writing of all ITGI Inventions. If ITGI requests, and at ITGI's sole expense, Institution will provide ITGI with reasonable assistance to obtain patents to any such ITGI Inventions, including causing the execution of any necessary assignments or other documents.

D. Institution hereby grants ITGI a paid-up non-exclusive royalty free world-wide license to all Institution Inventions developed under this Agreement for research purposes only, and a time-limited first option to negotiate an exclusive, world-wide royalty-bearing license for commercial purposes, including the right to grant sub-licenses, to all Institution Inventions under this Agreement and to Institution's entire right, title and interest in and to all Joint Inventions under this Agreement. Any such exclusive licenses will include a reasonable royalty based on the respective parties' contributions to the inventions and other terms which are typical in licenses of similar technology. ITGI shall execute its first option within one hundred and eighty (180) days of ITGI's receipt of written notice of said invention referencing the start of the one hundred and eighty days (180). In the event that ITGI fails to so notify Institution or elects not to obtain an exclusive license, then ITGI's option shall expire with respect to said invention, and Institution will be free to dispose of its interests in the invention in accordance with Institution policy. If the parties fail to reach agreement on the terms for an exclusive license for a particular Invention, then for a period of twelve (12) months thereafter Institution shall not offer to license the Invention to any third party on materially better terms than those last offered to ITGI without first offering such terms to ITGI, in which case ITGI shall have a period of thirty (30) days in which to accept or reject the offer.

14. **Notice**

Whenever any notice is to be given hereunder, it shall be in writing and mailed postage prepaid by certified or registered mail, return receipt requested, or personally delivered to the appropriate party at the address indicated in Exhibit A and incorporated into this Agreement by reference, or at such other place or places as either party may designate in a written notice to the other.

Notice shall be deemed to have been received at the earlier of receipt or five (5) days from the date of mailing (in the case of a letter).

15. **Assignment**

This Agreement is not assignable by Institution and any attempted assignment or delegation in violation hereof shall be void. ITGI may assign this Agreement to an affiliated company without the prior consent of Institution. Notwithstanding such assignment, ITGI shall remain liable for all of its obligations under this Agreement.

16. **Applicable Law**

This Agreement shall be construed in accordance with Texas law.

17. **Publicity**

Neither party shall make reference to the other in a press release or any other written statement in connection with the Study performed under this Agreement, if it is intended for use in the public media, except as required by the Texas Public Information Act or other law or regulation. Institution, however, shall have the right to acknowledge ITGI's support of the investigations under this Agreement in scientific or academic publications and other scientific or academic communications, without ITGI's prior approval. In any such statements, the parties shall describe the scope and nature of their participation accurately and appropriately.

18. **Independent Contractor**

It is agreed by the parties that Institution is acting in the capacity of independent contractor hereunder and not as employees, agents or joint venturers of or with ITGI. Institution does not have any authority to represent, bind or act on behalf of ITGI.

19. **Agreement Modifications**

Neither this Agreement nor the Protocol may be altered, amended or modified except by written document signed by both parties.

20. **Severability**

If any term or condition of this Agreement, the deletion of which would not adversely affect the receipt of any material benefit by either party hereunder, shall be held illegal, invalid or unenforceable, the remaining terms and conditions of this Agreement shall not be affected thereby and such terms and conditions shall be valid and enforceable to the fullest extent permitted by law.

21. **No Waiver**

Failure on the part of ITGI to exercise or enforce any right conferred upon it hereunder shall not be deemed to be a waiver of any such right nor operate to bar the exercise or enforcement thereof at any time or times thereafter.

22. **Force Majeure**

Noncompliance by either party with the obligations of this Agreement due to force majeure, (laws or regulations of any government, war, civil commotion, destruction of production facilities and materials, fire, flood, earthquake or storm, labor disturbances, shortage of materials, failure of public utilities or common carriers), or any other causes beyond the reasonable control of the applicable party, shall not constitute breach of this Agreement and such party shall be excused from performance hereunder to the extent and for the duration of such prevention, provided it first notifies the other party in writing of such prevention and that it uses its best efforts to cause the event of such force majeure to terminate, be cured or otherwise ended.

23. **Employee Obligations to Perform Services**

Institution represents that the Principal Investigator and all other investigators that may perform services hereunder are its employees and shall abide by the terms and conditions of this Agreement as if each were a party hereto.

24 **Entire Understanding**

This Agreement, including any exhibits and schedules hereto, constitutes the entire agreement between the parties with respect to the subject matter hereof. This Agreement supersedes and cancels all previous agreements among the parties, written and oral in respect of the subject matter hereof. In the event of any inconsistency between this Agreement and the Protocol, the terms of this Agreement shall govern except with regard to adverse event reporting procedures which shall be governed by the Protocol and any appendix or attachment thereto.

IN WITNESS WHEREOF, the parties have caused this Agreement to be executed, by duly authorized representatives, as of the Effective Date.

Signatures



EXHIBIT A

This Exhibit A hereby serves as an Addendum to the attached Investigator Initiated Master Clinical Trial Research Agreement and is incorporated therein and expressly made a part thereof. Accordingly, Institution's engagement is subject to the terms and conditions of the Investigator Initiated Master Clinical Trial Research Agreement and the following:

Study Drug:

Protocol Title:

("Exhibit B" attached hereto and incorporated hereby)

Principal Investigator:

Confidentiality Period: five (5) years from the termination of this Addendum.

Notice:

To Institution: [Insert applicable Institution Notice Information]

Attn.: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

To ITGI: Integrated Therapeutics Group, Inc.

Medical & Scientific Affairs

2000 Galloping Hill Road

Kenilworth, New Jersey 07033

Attn.: **[ENTER CONTACT NAME]**

Budget: (“Exhibit B” attached hereto and incorporated herein)

Unless expressly stated otherwise herein, all terms and conditions of the Investigator Initiated Master Clinical Trial Research Agreement shall remain in full force and effect.

IN WITNESS WHEREOF, the parties have caused this Addendum to Investigator Initiated Master Clinical Trial Agreement to be executed, by duly authorized representatives, as of the last date written below.

Signatures

I have read the Agreement and understand my obligations hereunder:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

[Insert Principal Investigator’s name]

Principal Investigator

Date\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_



EXHIBIT B

Protocol and Budget



EXHIBIT C

Contact List