MASTER CLINICAL TRIAL AGREEMENT

This Master Clinical Trial Agreement ("Agreement") is entered into on the last date of signature below (the "Effective Date") by and between **The University of Texas Health Science Center at San Antonio; The University of Texas Health Science Center at Houston; The University of Texas Health Science Center at Tyler; The University of Texas Medical Branch at Galveston; The University of Texas Southwestern Medical Center; and The University of Texas at Austin** ("Institution" or collectively, "Institutions"), each having a place of business as attached in Appendix A; and each a member institution of The University of Texas System ("System"), having a place of business at **201 West 7th Street, Austin, TX 78701,** and **Boehringer Ingelheim Pharmaceuticals, Inc.** ("BIPI"), having its principal location at **900 Ridgebury Road/P.O. Box 368, Ridgefield, CT 06877-0368.**

RECITALS

Whereas, BIPI is a pharmaceutical company that regularly sponsors and conducts clinical trials of various BIPI compounds (each a "BI Investigational Product") according to a specific clinical trial protocol for each clinical trial, including all documents attached thereto and referenced therein (each a "Protocol"); and

Whereas, BIPI seeks to engage the services of duly qualified institutions and investigators to conduct the clinical trials; and

Whereas, Institution has expertise in the area of health and medical research and desires to participate as a site for the conduct of one or more of the clinical trials, as contemplated by this Agreement; and

Whereas, Institution may, subject to written agreement between Institution and BIPI, participate as an investigative site in one or more clinical trials (each a "Trial" and collectively the "Trials"); and

Whereas, Institution engages employees and/or agents to conduct medical research on behalf of Institution and one such employee or agent, as mutually agreed upon by BIPI and Institution, will serve as the principal investigator in each Trial in which Institution participates, on behalf of Institution, and will conduct clinical investigations as part of such Trial, as contemplated by this Agreement ("Investigator"), but will not be considered a party to this Agreement.

Now, therefore, in consideration of the promises and mutual covenants contained herein, the parties agree as follows:

1. SCOPE

During the term of this Agreement, Institution and Investigator shall conduct each Trial in accordance with this Agreement and a fully executed Individual Clinical Trial Agreement, as set forth in Section 2 below. BIPI and Institution agree that Investigator is not a party to this Agreement or any ICTA (defined below).

2. INDIVIDUAL CLINICAL TRIAL AGREEMENT

The BI Investigational Product and specific requirements for each Trial shall be set forth in a separate "Individual Clinical Trial Agreement" ("ICTA") substantially similar to the form attached hereto as Exhibit A, and each Individual Clinical Trial Agreement shall include, without limitation, the information noted in Exhibit A and the attachment(s) referenced therein. The terms and conditions set forth in this Agreement shall apply to and govern each Individual Clinical Trial Agreement, except as expressly modified therein. With respect to each Trial, BIPI and Institution shall agree in writing to the terms of the Individual Clinical Trial Agreement. Additionally, for each ICTA which is

negotiated by an authorized agent or Contract Research Organization ("CRO") of BIPI, BIPI will, to the extent possible, direct such agent or CRO to honor and use the then-current Master Clinical Trial Agreement as between BIPI and Institution. The Parties understand and acknowledge that, in rare instances, BIPI's CRO may have to use a different template other than this Agreement. In such instances, BIPI will, to the extent possible, direct its CRO to conform its template with the substantive provisions in this Agreement. Institution shall be solely responsible for obtaining the necessary approvals, including IRB approval, for each Individual Clinical Trial Agreement and Protocol, as applicable. The Individual Clinical Trial Agreement may be modified only by a document signed by all relevant parties. For sake of clarity, the parties agree to amend this Master Agreement for substantive terms that apply to all Individual Clinical Trial Agreements under this Agreement. Also, any modifications made to an Individual Clinical Trial Agreements should be limited to terms or provisions for that specific Individual Clinical Trial Agreement.

3. OBLIGATIONS AND DUTIES OF INSTITUTION AND INVESTIGATOR FOR EACH TRIAL

3.1 Conduct of Trial. Investigator, acting through and as an employee of Institution, will conduct the Trial at the research facility set forth in the Individual Clinical Trial Agreement. For sake of clarity, Investigator is not a party to this Agreement but will acknowledge 'reading and understanding' his/her obligations under a specific Individual Clinical Trial Agreement as it relates to this Agreement. Institution will provide an adequate number of qualified staff and adequate facilities and will require such staff to conduct the Trial properly, safely, and in accordance with the Protocol, applicable laws and Institution's ethical standards and/or policy to the extent they are consistent with the terms of the Protocol, applicable laws or this Agreement or ICTA. Institution certifies it will use reasonable efforts to ensure that such staff will conduct the Trial in accordance with the Protocol and applicable laws without exception or deviation except as specifically set forth herein. Any and all research and procedures pertaining to the Trial will be performed only by the Investigator or other Institution personnel assigned thereto by Institution. Institution will personally supervise the work of all assigned personnel, and neither Institution nor Investigator may delegate this duty.

Notwithstanding the foregoing, Institution may delegate other duties of Investigator and/or duties of Institution and/or its assigned personnel under this Agreement and/or an Individual Clinical Trial Agreement to third-parties provided that (i) Investigator will personally supervise the work of the third-party; (ii) the third-party will only assign and/or delegate Trial related activities to its own employees; (iii) Institution will remain fully responsible for the performance of such third-parties under this Agreement and/or an ICTA, as applicable; (iv) Institution and the third-party have entered into a written agreement ("Side Agreement") that (1) binds such third-party to terms and conditions that are at least as stringent as those contained in this Agreement and the respective Individual Clinical Trial Agreement, including, but not limited to, those regarding Trial conduct, confidentiality, intellectual property, use of information, record retention, and monitoring, and (2) does not conflict with any of BIPI's rights and obligations under this Agreement or the respective Individual Clinical Trial Agreement; and (v) BIPI will be deemed a third-party beneficiary of the Side Agreement and will be entitled to enforce any applicable terms thereunder as related to this Agreement, the respective Individual Clinical Trial Agreement and/or the Trial.

Institution agrees to, and shall ensure that the Investigator will provide an up to date curriculum vitae for Investigator, any sub-investigators assigned to the Trial. If, for any reason whatsoever, Institution and/or Investigator become(s) unable to provide adequate qualified staff or adequate facilities, Institution and/or Investigator will notify BIPI, in writing, promptly. Nothing in this Agreement will limit the freedom of or prohibit Institution or any of its personnel, including the Investigator, from conducting any research or from performing research for or with any entity or person, including any other outside sponsors, provided that Institution agrees that any such undertakings will not limit its obligations here under and will not prevent it from fulfilling its obligations under this Agreement in a timely manner. The parties acknowledge that this provision is intended to preserve the academic freedom and integrity of Institution and its faculty and to ensure that Institution and its faculty are not regarded as exclusive researchers for BIPI.

3.2 Enrollment of Trial Subjects. Institution agrees to, and shall ensure that the Investigator will enroll subjects as participants in the Trial ("Trial Subjects") in accordance with the terms and conditions of the Protocol, this Agreement, and the applicable Individual Clinical Trial Agreement. Institution shall ensure that Investigator will enroll Trial Subjects in strict compliance with the exclusion and inclusion criteria set forth in the Protocol without deviation or exception. Institution agrees to and shall require the Investigator to ensure that all requirements for obtaining informed consent and privacy-related documents are satisfied and obtained from each Trial Subject prior to enrolling such subject in the Trial. Any individual who precisely meets the inclusion criteria set forth in the Protocol, and has signed the required informed consent will be enrolled in the Trial and included as a Trial Subject for purposes of this Agreement and the applicable Individual Clinical Trial Agreement. Institution, on behalf of itself and Investigator, acknowledges and agrees that enrollment may be competitive and, if so, will be closed when the desired number of evaluable Trial Subjects has been accumulated. Should Investigator have additional qualified subjects to participate as Trial Subjects which would exceed the maximum enrollment rate as noted in the Protocol or as otherwise identified by BIPI in writing, Investigator may enroll additional Trial Subjects only after Investigator obtains prior written approval from BIPI.

3.3 Submission to IRB. Institution shall ensure that Investigator will, where required by applicable law and/or the Protocol, submit the Protocol, as prepared by BIPI, for initial and continuing review and approval to the Institutional Review Board ("IRB") having jurisdiction over the conduct of the Trial. In the event the IRB requests changes, Institution will ensure that the Investigator will notify BIPI of such required change and BIPI will promptly make such change or contact the IRB for further discussion, provided, however, if after such discussion, BIPI does not make the change as required by the IRB and the IRB withdraws approval of the Trial, Institution shall have the right to terminate the ICTA pursuant to Section 6.4. Institution shall ensure that Investigator will ensure that any amendments to the Protocol made by BIPI are submitted to the IRB for review and/or approval by the IRB as may be required by applicable law and/or the Protocol. Institution shall ensure that Investigator will also (i) obtain and forward to BIPI evidence of IRB approval of or objections to the Protocol, any applicable amendments, and any required informed consent document(s) prior to beginning Investigator's enrollment of Trial Subjects; (ii) obtain and forward to BIPI evidence of ongoing review of the Protocol and informed consent document(s) by the IRB; and (iii) obtain and forward to BIPI evidence of IRB approval of any publicity, advertising or recruitment materials used for the Trial ("Advertising Materials") prior to the publication of or other use of such Advertising Materials. Any such informed consent document and Advertising Materials will also be subject to prior written approval of BIPI.

3.4 Publicity and Advertising. Except to the extent that disclosure is required by applicable law, Institution and/or Investigator will submit all Advertising Materials, regardless of content, format, media, or intended venue, to BIPI for written approval prior to use.

3.5 Qualification of Investigator and Successor Investigator. Institution will ensure that Investigator is qualified to conduct the Trial in accordance with this Agreement, the Individual Clinical Trial Agreement and the Protocol at all times during the term of this the Individual Clinical Trial Agreement. If the Investigator is, at any time, no longer qualified or is unable to perform any of the activities of the Trial, Institution and BIPI may mutually agree to a substitute Investigator. Institution will notify BIPI, in writing, promptly upon learning that the Investigator is or will be unable to perform any of the activities of the Trial. Institution will use its best efforts to identify and obtain a substitute Investigator who is ready, willing and able to assume the role of Investigator and who is acceptable to BIPI, promptly following such notice to BIPI. If an acceptable Investigator cannot be obtained, BIPI or Institution may, at their own discretion, immediately terminate the Individual Clinical Trial Agreement in accordance with Article 6 below. Prior to assuming the role of Investigator, the Institution shall ensure that the substitute Investigator shall review this Agreement and shall acknowledge in writing that he/she has read and understands all obligations, terms and conditions of this Agreement and the applicable Individual Clinical Trial Agreement.

3.6 Responsibility for BI Investigational Product. In addition to the BI Investigational Product, BIPI may provide or arrange for provision of other drug products, if applicable, to be used in the Trial in accordance with the Protocol (the BI Investigational Product and such other drug products being supplied to Institution and/or Investigator pursuant to an Individual Clinical Trial Agreement collectively referred to herein as "Trial Drug"). BIPI represents that the Trial Drugs have been manufactured in accordance with Current Good Manufacturing Practices in the United States of America. Institution and Investigator will be responsible for storing the Trial Drug in a secure, limited access area under appropriate climate conditions specified in the Protocol and for accounting for all Trial Drug whether or not such Trial Drug is used. Institution and Investigator will ensure that the Trial Drug is administered only to Trial Subjects in strict accordance with the Protocol and only under the supervision of Investigator. Neither Institution nor Investigator will transfer any Trial Drug to any other party without the prior written approval of BIPI and the appropriate documentation supporting the chain of custody of the Trial Drug. Any Trial Drug remaining in either Institution's or Investigator's possession upon termination of this the Individual Clinical Trial Agreement or completion of the Trial by Institution and Investigator, will be returned to BIPI, at BIPI's expense, within sixty (60) days following termination or completion. At no time will any Trial Drug be employed for any purpose other than as described in the Protocol.

3.7 Adverse Event Reporting. Institution shall ensure that Investigator will collect and report information on all adverse events, serious and non-serious, as defined in the Protocol, that occur for each Trial Subject ("Adverse Events") from the point the Trial Subject signs the informed consent until completion of the Trial, including any post treatment period specified in the Protocol, in accordance with the instructions provided in the Investigator Site File, (as defined by the ICH GCP Guidelines, defined below), applicable law and any condition of approval imposed by the IRB or the United States Food and Drug Administration ("FDA"). The Investigator must report any serious Adverse Event ("SAE") as herein described, to BIPI within twenty-four (24) hours or the next business day, whichever is shorter, in accordance with the Protocol. The Investigator also must report to BIPI information on any SAE of which Investigator becomes aware that occurs at any time after Trial completion by the Trial Subject, if the Investigator suspects a causal relationship to the Trial Drug and the Study. The Investigator will attempt to collect and report to BIPI follow up information on SAEs as requested by BIPI in the same manner.

3.8 Compliance. Institution and Investigator acknowledge that the Protocol will be provided to and reviewed by Investigator. Institution and Investigator will at all times conduct the Trial consistent with sound scientific procedures and in accordance with this Agreement, the Individual Clinical Trial Agreement and Exhibits thereto, including without limitation the Standard of Care Flowchart, Institution's ethical standards and/or policy to the extent they are consistent with the terms of this Agreement, the Protocol, the International Conference on Harmonisation Harmonised Tripartite Guideline for Good Clinical Practice ("ICH GCP Guidelines"), the principles laid down in the Declaration of Helsinki, current version (as long as local laws do not require to follow other versions), the Department of Health and Human Services Health Insurance Portability and Accountability Act Federal Regulations, any conditions imposed by the IRB or the FDA, and any and all other applicable and relevant laws and national, state or local regulatory requirements. Institution agrees to, and shall require the Investigator to, conduct the Trial in accordance with the Investigator Responsibilities – Protecting the Rights, Safety and Welfare of Study Subjects issued by the FDA in October 2009. Institution will be responsible for any breach of the terms and conditions of this Agreement, including, but not limited to, obligations of confidentiality, by an employee, representative, or agent of Institution.

BIPI requires Institution and Investigator to fully comply with all applicable disclosure obligations required by applicable law or regulation regarding Investigator's relationship with BIPI that may be externally imposed on Investigator based on Investigator's affiliation with any formulary or pharmacy and therapeutics committees or committees associated with the development of clinical guidelines, treatment protocols or standards, as well as any disclosure obligations which are required by any health care institution, medical committee, or other medical or scientific organization ("Committee"). To the extent required by such Committee, Institution shall and will ensure that

Investigator also discloses to such Committee the nature of Investigator's relationship with BIPI. This disclosure requirement set forth above extends two (2) years beyond the term of the Individual Clinical Trial Agreement. If participation on the Committee by Investigator creates the appearance of impropriety on behalf of BIPI, BIPI reserves the right to terminate this Agreement upon written notice pursuant to Section 6.2 of this Agreement.

Institution and Investigator acknowledge that BIPI has entered a Corporate Integrity Agreement ("CIA") with the Office of Inspector General of the U.S. Department of Health and Human Services ("OIG"). A copy of the BIPI CIA is located on the OIG website at http://oig.hhs.gov/compliance/corporate-integrity-agreements/cia-documents.asp. Neither BIPI nor Institution believes that the scope of this Agreement or any Individual Clinical Trial Agreement would render Institution, Investigator, or any Institution employee involved in the Trial a Relevant Covered Person under the CIA. Pursuant to the CIA, in the event that Institution, Investigator, and/or any Institution employee performing the individual Trial on behalf of Institution provides Covered Functions under this Agreement and becomes a Relevant Covered Person as defined in Section II.C.21. of the CIA, then BIPI, Institution, Investigator, and/or any Institution employee performing the individual Trial on behalf of Institution shall discuss and agree to comply with (i) BIPI Code of Conduct; (ii) BIPI's Compliance Program and applicable policies and procedures; (iii) all applicable federal health care program requirements; (iv) FDA requirements; and (v) all certification, training, and screening requirements of Sections III.B, C and F. of the CIA within thirty (30) days after becoming a Relevant Covered Person. A copy of BIPI's Code of Conduct and Corporate Compliance Program is available at http://us.boehringer-ingelheim.com/our_responsibility/responsible_business_practices.html. For clarification, a "Relevant Covered Person" does not include part-time or per diem contractors, subcontractors, agents, or other person who are not reasonably expected to work more than 160 hours per year for BIPI. Notwithstanding the foregoing, BIPI and Institution agree that as of the date hereof, Institution and its employees, including Investigator, are not providing and do not intend to provide Covered Functions in connection with this Agreement and are not Relevant Covered Persons. In the event Institution or any of its employees, including Investigator, in connection with this Agreement, might perform services approaching the threshold level to meet the definition of Covered Functions and/or become a Relevant Covered Person, the parties will cooperate to use best efforts to assure that said threshold level is not exceeded.

3.9 Emergency Deviations. Without limiting the foregoing, Institution shall ensure that Investigator will not deviate from the Protocol in any manner whatsoever unless (i) such deviation is required by the IRB or is, within the best medical judgment of the Investigator, necessary to treat a condition that poses an immediate risk to the life or physical well-being of a Trial Subject, and (ii) the Investigator has insufficient time to obtain BIPI approval, in any form whatsoever, prior to the deviation ("Emergency Deviation"). Investigator and/or his designee will (1) notify BIPI of any Emergency Deviation as soon as possible but not later than the next business day after the Emergency Deviation and (2) document the rationale for and the person authorizing each such Emergency Deviation, and (3) provide such documentation to BIPI and any applicable regulatory authorities promptly following such Emergency Deviation.

3.10 Non-emergency Additional Treatment. With the exception of Emergency Deviations, in the event Investigator determines, in his or her best medical judgment, that additional treatment or treatment that deviates from the Protocol is necessary to protect the non-emergency health, safety or welfare of a Trial Subject and such treatment (i) furthers Protocol objectives but is not is set forth in the Protocol; (ii) is contrary to or contraindicated by Protocol; or (iii) otherwise deviates from the Protocol ("Non-Emergency Additional Treatment"), Investigator must first notify BIPI in writing of such proposed Non-Emergency Additional Treatment. BIPI may, at its sole discretion, amend the Protocol to allow for such Non-Emergency Additional Treatment or otherwise approve of such Non-Emergency Additional Treatment in writing, subject to any required IRB approval. BIPI will be responsible for the reasonable and customary costs associated with such approved Non-Emergency Additional Treatment. In the event BIPI is not notified of such Non-Emergency Additional Treatment and/or does not approve of the Non-Emergency Additional Treatment in writing, BIPI reserves the right not to pay for the treatment. Further, in such

event, BIPI may require that Investigator remove such Trial Subject from participation in the Trial following such Non-Emergency Additional Treatment. Nothing contained herein shall require Institution or Investigator to give BIPI prior notification when providing the Trial Subject with routine clinical care that is not listed in the Protocol and that is not contrary to or contraindicated by the Protocol. Nothing contained herein shall limit the reimbursement of costs of treatment related to Trial Subject injury pursuant to Article 14 below.

3.11 Documents, Case Report Forms, and Final Data Submission. Institution and Investigator will maintain Trial documents in accordance with Article 10 of this Agreement, and the Individual Clinical Trial Agreement. Institution and/or Investigator will provide to BIPI copies of case report forms ("CRFs") or electronic case report forms ("eCRFs"), as applicable, for each Trial Subject and other such reports when and as required by the Protocol or applicable law. Within ninety (90) days following the completion of the Trial by Institution and Investigator, or the earlier termination of the Individual Clinical Trial Agreement or this Agreement, Institution shall ensure that Investigator will, to the extent permitted by law, the ICF and or authorization form, and the IRB, provide to BIPI any and all Trial data required pursuant to the terms of this Agreement, the respective Individual Clinical Trial Agreement, and the Protocol.

3.12 Time. Institution will and will ensure that Investigator exercises reasonable efforts to start and complete the Trial within the timeframe required by BIPI.

4. OBLIGATIONS AND DUTIES OF BIPI

4.1 Supply of Trial Drug. BIPI will supply the BI Investigational Product, if applicable, for use in the Trial at no cost to Institution or Investigator. BIPI may also supply or arrange for the provision of any other Trial Drug to be used in the Trial at no cost to Institution or Investigator, either through provision of such Trial Drug by BIPI or reimbursement to Institution.

4.2 Inform Investigator. For each Trial, prior to the start of the Trial, BIPI will provide Investigator with a current Investigator Brochure containing information about the chemical, pharmaceutical, toxicological, pharmacological and clinical data concerning the Trial Drug.

4.3 Compensation.

(a) Budget. In support of the services performed under the Individual Clinical Trial Agreement, BIPI will compensate Institution at fair market value as set forth in an itemized Clinical Trial Budget and Payment Schedule which shall be attached as Exhibit I to the Individual Clinical Trial Agreement ("Clinical Trial Budget"). If the Protocol is amended and such amendment impacts the compensable activities, the compensation may be adjusted accordingly by a written amendment to the Individual Clinical Trial Agreement executed by all of the parties. Such amounts are fully inclusive for all services provided by Institution and Investigator in connection with the Trial and include all applicable direct and indirect costs, overhead, fees and other assessments due from BIPI to Institution, Investigator and other persons or entities providing any services or goods in connection with the Trial, but does not include standard of care costs. BIPI will not make any payment to any individual or entity, including, but not limited to, Investigator, that is in violation of any applicable federal or state statute, regulation or guideline.

(b) Administrative Start-up Fees. BIPI will pay non-refundable administrative startup fees set forth in the Clinical Trial Budget with 100% of the fee to be paid after execution of the Individual Clinical Trial Agreement.

(c) Payment for Trial Visits and Milestones. BIPI will compensate Institution for completed Trial Subject visits and/or milestones according to the Clinical Trial Budget. Payment for any Trial Subjects that exceed the maximum enrollment rate for the specific Trial, if any, that are properly approved by BIPI pursuant to

Section 3.2 of this Agreement will be reimbursed at the same per visit amounts noted in the Clinical Trial Budget. No payments will be made for Trial Subjects who do not precisely meet the inclusion criteria set forth in the Protocol or who have otherwise been admitted to the Trial in violation of or outside the scope of the Protocol, unless otherwise agreed to in writing by BIPI.

Payment for specific procedures is contingent upon Institution's compliance with this Agreement, the ICTA and the Protocol, completion and submission of CRFs as reasonably directed by BIPI in writing, timely data query resolution, provided such resolution is reasonably requested by BIPI, and maintenance of Trial Drug accountability logs, as reasonably directed by BIPI in writing. Except as specifically agreed to by BIPI in writing, neither Institution, Investigator, nor any other person or entity will be entitled to any payments in connection with the Trial or activities conducted pursuant to this Agreement and/or the Individual Clinical Trial Agreement in addition to the amounts set forth in the Clinical Trial Budget.

(d) Screen Failures and Incomplete Trial Subjects. BIPI will pay Institution for a Trial Subject's visits which occur prior to a screen failure, as set forth in the Protocol ("Screen Failures") according to the Clinical Trial Budget. If a Trial Subject withdraws or is withdrawn from the Trial prior to completion ("Incomplete Trial Subject"), BIPI will pay Institution the pro rata costs per Trial Subject as set forth in the Clinical Trial Budget. Notwithstanding the foregoing, BIPI will not pay for Screen Failures or Incomplete Trial Subjects that have only signed the informed consent form and have not commenced other activities related to participation in the Trial. BIPI reserves the right to not pay for a Screen Failure or Incomplete Trial Subject if (i) BIPI reasonably determines that the Trial Subject did not precisely meet the inclusion criteria set forth in the Protocol at the time of enrollment and that the exclusion of such Trial Subject should have been clearly evident to Investigator through the exercise of reasonable pre-screening practices, or (ii) Institution's or Investigator's violation of the Protocol, other than for Emergency Deviations, caused the Trial Subject's screen failure or withdrawal. Notwithstanding the aforementioned, Institution shall be reimbursed by BIPI a Trial Subject consent fee, which amount will be included in the Clinical Trial Budget, where Institution attempted to enroll a Trial Subject in good faith if such Trial Subject elects to withdraw prior to any screening procedures being performed.

(e) Overpayments During the Course of the Trial. If during the course of the Trial BIPI compensates Institution any funds in excess of the amount due under the Clinical Trial Budget, Institution will return such excess funds to BIPI within sixty (60) days of written notification by BIPI to Institution or Institution's discovery of such overpayment, whichever first occurs.

(f) Hold-back, Final Accounting and Payment. To the extent set forth in the Clinical Trial Budget, BIPI may hold-back a percentage of all payments due to Institution, except for start-up fees, and pass-through costs specified in the Clinical Trial Budget, until Institution's completion of the Trial. Final payment hereunder will be expressly conditioned upon receipt by BIPI of any and all required data or other information from Institution and Investigator in a timely manner and as required by this Agreement, the Individual Clinical Trial Agreement, and/or the Protocol, in a form satisfactory to BIPI.

To the extent set forth in the Clinical Trial Budget, the final payment will be processed after BIPI's close-out visit to Institution, when all CRFs/eCRF's have been completed and logged for all Trial Subjects enrolled at Institution, all queries to Institution have been resolved, and Institution's data has been reviewed and accepted by the BIPI clinical monitor. The final payment will include any remaining approved interim patient Visit fees and/or any remaining approved invoiceable items noted on the Clinical Trial Budget (e.g., variable fees, repeat visits (if any)).

All final demands must be made for payment within eighteen (18) months of termination of this Agreement or completion of the Trial by Institution and Investigator.

(g) IRB Fees. If Institution uses a local IRB for the Trial, BIPI will reimburse Institution according to the Clinical Trial Budget for the actual IRB fees incurred. Institution must provide BIPI supporting documentation for such costs.

(h) Advertisement for Subject Recruiting. BIPI will provide Institution the funds set forth in the Clinical Trial Budget to cover costs for design, production, media, and postage for print, electronic, direct mail, and event costs associated with recruiting advertisements. All Advertising Materials must be approved by the IRB and BIPI in accordance with Section 3.3 and 3.4.

(i) SAE and IND Safety Reporting. BIPI will pay Institution for SAE and IND safety reporting according to the Clinical Trial Budget.

(j) Protocol Amendments. If the Protocol is amended and such amendment impacts the compensable activities, the compensation may be adjusted accordingly by a written amendment to the Individual Clinical Trial Agreement executed by all of the parties.

(k) Trial Subject Stipends. In the event the Clinical Trial Budget provides for the payment of a stipend to Trial Subjects, Institution and/or Investigator will pay Trial Subjects the exact amount set forth in the Clinical Trial Budget and will not, under any circumstances, reduce or supplement the stipend.

(l) Reporting of Payments. Pursuant to applicable laws, drug and device manufacturers are required to report data annually on fees, meals, educational items, other payments and items or transfers of value ("Payments") provided to health care professionals ("HCPs") and health care organizations ("HCOs"). Institution and Investigator understand that to comply with these reporting obligations, as well as other relevant state and federal laws, other legal requirements, and/or BIPI's CIA, BIPI may be required to report direct or indirect Payments made by BIPI under the Individual Clinical Trial Agreement. Institution and Investigator consent to having such Payment and corresponding information (including, without limitation, such personally identifiable information as Institution/Investigator name, address, and form of Payment and other information as may be required by law, regulation, other legal requirement or the CIA) reported for these purposes as may be required by law, regulation, other legal requirement or BIPI's CIA. To the extent BIPI is legally required to report such Payment information, Institution agrees to use commercially reasonable efforts to provide BIPI with information required by such applicable laws, and/or regulations under the Physician Payments Sunshine Act, Section 6002 of the Affordable Care Act of 2010 (Sunshine) or as otherwise mandated by applicable federal laws and/or regulations, state laws and/or regulations, BIPI's CIA, or other legal requirements. The reports shall be generated in a manner and at timeframes mutually agreed upon by the parties and as appropriately consistent with the final Sunshine regulations, federal and/or state law and/or regulations or other legal requirements, as applicable.

(m) Invoices. Institution shall invoice BIPI in accordance with the requirements set forth in the Clinical Trial Budget.

(n) Payee. All payments will be made by BIPI, as specified in the Form W-9 provided by Institution, payable to Payee as specified in Section V. of the ICTA.

4.4 Reporting of Safety Related Findings. Institution and BIPI will promptly notify each other upon identifying any aspect of the Protocol, including information discovered during site monitoring visits, or the Trial results that may adversely affect the safety, well-being, or medical care of Trial Subjects, or that may affect the willingness of subjects to continue participation of the Trial, influence the conduct of the Trial, or that may alter the IRB's approval to continue the Trial. Institution shall promptly notify the IRB of any such events. If BIPI conducts monitoring visits or remote monitoring activities, BIPI will, at the time of the audit closeout visit or upon the completion of any inspection, notify Institution of any monitoring findings that could affect the safety of Trial Subjects or influence

the conduct of the Trial. When BIPI has the responsibility to conduct data and safety monitoring, BIPI shall include a plan for data and safety monitoring for the Trial in the Trial Protocol. In accordance with 21 C.F.R. § 312.50, 21 C.F.R. §312.55, and the FDA's Guidance on Adverse Event Reporting to Institutional Review Boards in Clinical Trials (January 2009), BIPI shall promptly notify Institution of new observations discovered by or reported to BIPI on the Trial Drug, particularly with respect to adverse effect and safe use, and shall ensure that Investigator is promptly informed of significant adverse effects or risks with respect to the Trial Drug. Institution shall promptly report to the IRB, in writing, any such information. For a period of two years following the conclusion of the Trial, BIPI shall notify Investigator of any findings that could directly affect the safety of Trial Subjects. When Trial Subjects' safety or medical care could be directly affected by Trial results, then notwithstanding any other provision of this Agreement, Institution will send Trial Subjects a written communication about the results.

1/25/2016
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5. REPRESENTATIONS AND CERTIFICATIONS OF INSTITUTION AND INVESTIGATOR

5.1 Tax I.D. No and ACH Information. Institution represents and certifies that it has verified that the Payee and Tax I.D. number set forth in the ICTA are correct and match the information listed with the Internal Revenue Service.

5.2 Debarment, Exclusion, and Standing. Institution represents and certifies that, to the best of its knowledge after reasonable inquiry, Institution, Investigator and any sub-investigators involved in the Trial, have not been restricted, disqualified or debarred from conducting clinical studies by the FDA or any other applicable governmental regulatory agency and are not the subject of a Notice of Initiation of Disqualification Proceedings and Opportunities to Explain ("NIDPOE") letter or Notice of Opportunity for Hearing ("NOH") from the FDA. Institution will notify BIPI promptly in writing if Institution, Investigator or such sub-investigators is so restricted, disqualified or debarred or becomes the subject of an NIDPOE letter or NOH during the course of the Trial.

Institution represents and certifies that, to the best of its knowledge after reasonably inquiry, except as provided to BIPI in writing, no investigation or trial in which Investigator has served as the principal investigator at Institution has been terminated for Investigator's failure to adhere to federal or state laws or regulations. Institution will notify BIPI immediately in writing if any trial in which Investigator is or has served as the principal investigator at Institution has been terminated for reasons listed above during the course of the Trial and such termination would affect the Investigator's ability to perform the Trial. In either such event, BIPI may immediately terminate this Agreement or the applicable Individual Clinical Trial Agreement in accordance with Article 6 below.

Institution represents and certifies that, to the best of its knowledge after reasonable inquiry, Institution, Investigator, and Institution's employees, contractors, and agents involved in the conduct of the Trial are not currently excluded, debarred, suspended, or otherwise ineligible to participate in Medicare, Medicaid, and/or any Federal healthcare programs or Federal procurement or nonprocurement programs or has been convicted of a criminal offense that falls within the scope of 42 U.S.C. 1320a-7(a), but has not yet been excluded, debarred, suspended, or otherwise declared ineligible. Without limiting the foregoing, Institution represents and certifies that Institution, Investigator, and Institution's employees, contractors, and agents involved in the conduct of the Trial have been screened on the following lists: (i) the HHS/OIG List of Excluded Individuals/Entities at http://www.oig.hhs.gov; and (ii) the General Services Administration List of Parties Excluded from Federal Programs at http://www.epls.gov. Institution will notify BIPI immediately in writing if Institution, Investigator, or any of their Institution's employees, contractors, and agents involved in the conduct of the Trial is so excluded, debarred, suspended, otherwise ineligible to participate in Medicare, Medicaid, and/or any Federal healthcare programs or Federal procurement or nonprocurement programs or has been convicted of a criminal offense that falls within the scope of 42 U.S.C. 1320a-7(a), but has not yet been excluded, or is recommended for exclusion or debarment. BIPI may immediately terminate this Agreement or the applicable Individual Clinical Trial Agreement in accordance with Article 6 below if, during the

course of this Agreement, Institution, Investigator, or any of Institution's employees, contractors, or agents involved in the conduct of the Trial is so excluded or debarred or is recommended for exclusion or debarment. .

Institution further represents and certifies that, to the best of its knowledge after reasonable inquiry, Institution, their respective employees, contractors, and agents involved in the conduct of the Trial are appropriately licensed with no licensure restrictions and are in good standing within their applicable professional community. Institution will notify BIPI immediately in writing if Institution, Investigator, or any of Institution's employees, contractors, or agents involved in the conduct of the Trial is and/or becomes unlicensed, has restrictions placed on such license, or loses standing within their applicable professional community during the course of this Trial. BIPI, in its sole discretion, may immediately terminate this Agreement the applicable Individual Clinical Trial Agreement in accordance with Article 6 below if, during the course of this Trial, Institution, Investigator, or any of Institution's employees, contractors, or agents involved in the conduct of the Trial is and/or becomes unlicensed, has restrictions placed on such license, or loses standing within their applicable professional community.

Failure to comply with the representations and certifications of this Section 5.2 and/or provide notice of events described in this Article shall constitute grounds for immediate termination of this Agreement or the applicable Individual Clinical Trial Agreement by BIPI, in its sole discretion, in accordance with Article 6 below.

5.3 Anti-bribery and Anti-corruption. Institution represents and certifies that it has complied and at all times will comply with the requirements of all other applicable anti-bribery and anti-corruption laws and regulations including, without limitation the United States Foreign Corrupt Practices Act, as amended (the "FCPA"), the United Kingdom Bribery Act of 2010 as amended (the "UKBA"), each to the extent applicable to Institution. Without limiting the generality of the foregoing, Institution represents and certifies that it and its employees have not and will not, in violation of any applicable laws and regulations, improperly make, pay, offer to pay, promise, or authorize, directly or indirectly, the payment of money or anything of value to anyone, including but not limited to Government Officials, as defined below, in order to improperly influence, obtain, or retain approvals, licenses, secure improper advantages, or business in connection with the services provided under this Agreement. Institution will immediately notify BIPI if it learns that any such improper payment, offer, promise, or authorization has been made, directly or indirectly, in violation of any applicable laws and regulations. BIPI may reasonably request from time to time, the Institution certify compliance with the foregoing. As used herein, "Government Official" means any officer or employee of a government or any department, agency, or instrumentality thereof (including officers and employees of government-owned entities or public international organizations), any person acting in an official capacity for or on behalf of any government entity or official, or any political party, or party official.

Institution represents and certifies that if it learns any information giving it a good faith reasonable belief that Institution or its employees has or may have violated any applicable anti-bribery and anti-corruption law or regulation, Institution will promptly notify BIPI in writing.

5.4 Authorization. Each of Institution and BIPI represents and certifies that this Agreement has been duly authorized, executed and delivered by such party. Each of Institution and BIPI represents and certifies that this Agreement represents the legal, valid and binding agreement of such party and is enforceable against such party in accordance with its terms. Each of Institution and BIPI represents and certifies that the person executing this Agreement on its behalf is authorized by such party and its governing board or management committee to do so and that the execution hereof is the binding and enforceable act of such party. Institution represents and certifies that as the employer of Investigator, it is authorized to and agrees that it will require Investigator to comply with the terms and conditions of this Agreement and the applicable Individual Clinical Trial Agreement.

5.5 No Violation. Institution and BIPI each represents and certifies that the execution, delivery and performance of this Agreement by it does not (i) require the consent, waiver, approval, license or authorization of any person or public authority which has not heretofore been obtained; (ii) violate any provision of law applicable to it; (iii)

conflict with or result in a default under any agreement or instrument to which it is a party or by which it is bound; or (iv) violate any judicial or administrative decree, regulation or any other restriction of any kind or character to which it is a party or by which it is bound.

5.6 Conflict of Interest. Institution represents and certifies that neither Institution nor Investigator have any conflict of interest that would affect conduct of the Trial and that neither Institution nor Investigator have received any extra benefits from BIPI or a BIPI affiliated party for participation in the Trial. Institution will promptly notify BIPI in writing if any such conflict of interest arises during the term of this Agreement.

6. TERM AND TERMINATION

6.1 Term. The initial term of this Agreement (the "Initial Term") shall commence on the Effective Date and continue for a period of five (5) years thereafter. Notwithstanding the foregoing, upon termination of this Agreement, any on-going Trial shall continue to be subject to the provisions of this Agreement and the applicable Individual Clinical Trial Agreement until all activities in conduct of the Trial as provided in the Protocol are concluded. This Agreement may be renewed by mutual written consent of Institution and BIPI for such additional period as the Parties may agree upon in writing.

6.2 Termination on Notice by BIPI. BIPI may terminate this Agreement or the conduct of any Trial under an Individual Clinical Trial Agreement and enrollment or randomization of Trial Subjects for any reason upon at least thirty (30) days prior written notice to Institution and/or Investigator. The date of termination will be the date specified in such notice.

6.3 Immediate Termination or Suspension by BIPI for Cause. BIPI may terminate an Individual Clinical Trial Agreement or terminate or suspend enrollment or randomization of Trial Subjects immediately upon notice to Institution and Investigator if (i) the Institution or Investigator fails to meet enrollment goals of the Trial within the timeframe, if any, specified by BIPI; (ii) BIPI becomes aware of any efficacy or safety information that could significantly affect or alter continuation of the Trial, (iii) BIPI terminates its conduct of the entire Trial in BIPI's sole discretion; or (iv) there is a violation or a suspected violation by Institution or Investigator of any applicable laws and regulations, ICH GCP Guidelines, the Protocol or this Agreement, as determined within BIPI's reasonable discretion. The date of termination will be the date specified in such notice.

6.4 Termination or Suspension by Institution for Cause. Institution may terminate this Agreement or an Individual Clinical Trial Agreement effective upon written notice to BIPI if BIPI materially breaches any of the terms or conditions of this Agreement or the Individual Clinical Trial Agreement, as applicable, and fails to cure such breach within thirty (30) days after Institution provides written notice of such breach alleged by Institution. Additionally, Institution may terminate this Agreement or an Individual Clinical Trial Agreement in the event the FDA or IRB withdraws its approval of the Trial. Additionally, Institution shall be entitled to immediately terminate an Individual Clinical Trial Agreement (i) for health, safety or regulatory reasons, or (ii) if the Principal Investigator is no longer employed by Institution, or (iii) if the Principal Investigator is no longer able to perform his or her obligations due to family, health or medical reasons, provided however, that before terminating the Agreement on the basis of (ii) or (iii) above, Institution will make a good faith effort to find a substitute researcher who is ready, willing and able to assume the role of Principal Investigator and complete the Study and who is acceptable to BIPI. In such event of (i) above, Institution will promptly notify BIPI of any such indication and its determination to suspend enrollment of Trial Subjects at its site but will continue to perform follow-up procedures as set forth in Section 6.5(c) below.

6.5 Effects of Termination. The effect of any such termination will be as follows:

(a) If this Agreement is terminated, this Agreement, all Individual Clinical Trial Agreements and all rights, obligations, liabilities and responsibilities of the parties will terminate on the termination date except that those rights, obligations, liabilities and responsibilities that survive pursuant to Section 21.2 will terminate upon completion of each party's obligations hereunder and under the applicable Individual Clinical Trial Agreement, except that any all Individual Clinical Trial Agreements executed before the effective date of termination of this Agreement shall remain in effect until terminated or expired in accordance with the terms therein.

(b) If an Individual Clinical Trial Agreement is terminated, all rights, obligations, liabilities and responsibilities of the parties thereunder will terminate upon completion of each party's obligations thereunder.

(c) If enrollment or randomization of Trial Subjects has begun in a Trial conducted by Institution and Investigator under an Individual Clinical Trial Agreement is terminated, Institution and Investigator will terminate enrollment and will terminate treatment of all Trial Subjects pursuant to the Protocol. Following such termination, Institution and Investigator will continue to monitor Trial Subjects and maintain clinical data to the extent required by the Protocol and in accordance with ICH GCP Guidelines, but only to the extent payment to cover such monitoring and maintenance expenses is included in the Clinical Trial Budget.

(d) If enrollment or randomization of Trial Subjects has begun and enrollment or randomization of additional Trial Subjects is terminated or suspended under an Individual Clinical Trial Agreement, Institution and Investigator will either terminate or suspend enrollment with respect to that Individual Clinical Trial Agreement, as appropriate, and will continue to conduct the Trial in accordance with the Protocol, the Individual Clinical Trial Agreement, and this Agreement for all Trial Subjects then enrolled.

(e) For a particular Trial, Investigator will (i) provide to BIPI any and all data required pursuant to the terms of this Agreement, and/or pursuant to the applicable Individual Clinical Trial Agreement that have been generated or accumulated as of the termination date, and/or pursuant to the Protocol that have been generated or accumulated as of the termination date, and (ii) subject to Section 11.1, provide BIPI representatives access, both prior to and for a reasonable period following final payment, to all Trial data generated or accumulated as of the termination date and access to relevant medical records for review and completion of necessary documentation and appropriate transfer or discontinuation of Trial Subjects' participation in such Trial.

(f) Upon early termination for any reason, Institution and Institution will ensure that Investigator will use their/his/her reasonable efforts to promptly limit or terminate any outstanding commitments and to conclude the work. All costs incurred by Institution prior to such termination and authorized under the Protocol and Clinical Trial Budget will be reimbursable, including, without limitation, all non-reimbursable costs and non-cancelable commitments incurred in accordance with the Clinical Trial Budget prior to the receipt of the termination notice. In the event of early termination, final accounting and payments will be made in accordance with Section 4.3.

Notwithstanding the foregoing, if an Individual Clinical Trial Agreement is terminated by BIPI pursuant to Sections 6.3(i) or 6.3(iv), Institution will only be entitled to payment for costs and commitments relating to work completed by Institution and Investigator prior to termination.

7. CONFIDENTIAL INFORMATION

7.1 Definition of Confidential Information. As used herein, "BIPI Confidential Information" means:

(a) any and all

(i) written, verbal, or electronic

(1) information of a scientific, business, technical, non-technical, or other nature;

(2) know-how;

(3) data;

(ii) Trial Results (as defined in Section 8.2 below)

(b) that relates to the Trial, a Trial Drug, and/or BIPI or an Affiliate of BIPI, or BIPI's or a BIPI Affiliate's products, inventions, plans, and/or processes; and

(c) that may be disclosed or given to Institution and/or Investigator by BIPI during the term of this Agreement or an Individual Clinical Trial Agreement or that is collected, prepared, developed or generated by Institution, Investigator, or any other person or entity on behalf of Institution, pursuant to this Agreement or that arises pursuant to the conduct of an individual clinical Trial, except as otherwise specified in this Agreement, including Trial Results (as defined in Section 8.2 below). Notwithstanding anything to the contrary, Confidential Information excludes Institution Records (as defined in Section 8.3 below), Source Documents (as used in Section 8.3 below), original medical records or any other information that is required by law or regulation to be retained by Institution.

Subject to Institution's right to publish as set forth in Section 9 and Institution's right to use Intellectual Property as set forth in Section 8, BIPI Confidential Information includes, but is not limited to, this Agreement, all Individual Clinical Trial Agreements, all Protocols, information, data, know-how, chemical or biological samples, compositions, formulations, specifications, systems, techniques, analyses, production and quality control data, research data, development data, clinical data, testing data, promotional materials, marketing and financial data, and such other information or data relating to BIPI, provided by BIPI to Institution under this Agreement, including reports, inventions, and work product.

As used in this Agreement, an "Affiliate" of BIPI shall mean any company or business entity which controls, is controlled by, or is under common control with BIPI. For purposes of this definition, "control" shall mean the possession, directly or indirectly of the power to direct or cause the direction of the management and policies of an entity (other than a natural person), whether through the majority ownership (> 50 %) of voting capital stock, by contract or otherwise.

BIPI Confidential Information does not include information that:

(i) Institution and/or Investigator can prove by written documentation was known to Institution and/or Investigator prior to the date of this Agreement or the Individual Clinical Trial Agreement, as applicable, and is not subject to any confidentiality restrictions at the time of disclosure to Institution;

(ii) at the time of disclosure was generally available to the public, or which after disclosure becomes generally available to the public through no fault of the Institution or Investigator; or

(iii) Institution and/or Investigator can prove by written documentation was lawfully obtained from a third party without any obligation of confidentiality to BIPI and which was not obtained directly or indirectly from BIPI or a BIPI Affiliate.

(iv) is recorded in the Trial Subject's medical records or original Source Documents (as defined Good Clinical Practice: Consolidated Guidelines published by the Food and Drug Administration) in accordance with the applicable standard(s) of care or more stringent policy of Institution; or

(v) information that is independently developed by Institution without reference to or the use of BIPI's Confidential and Proprietary Information; or

(vi) information required to be disclosed in order to obtain the informed consent from patients or subjects who may wish to enroll in the Trial, provided, however, that the information will be disclosed only to the extent necessary and will not be provided in answer to unsolicited inquiries by telephone or to individuals who are not eligible Trial candidates; or

(vii) is contributed and generated by Institution and/or published in accordance with Section 9.2.

7.2 Limitation on Use and Disclosure. During the term of this Agreement and for a period of seven (7) years following its termination, neither Institution nor Investigator, nor any employee, representative or agent of Institution, will, without BIPI's prior written consent or as may be expressly permitted by this Agreement, disclose to any third party any BIPI Confidential Information or use such BIPI Confidential Information for any purpose other than its obligations under this Agreement. Institution and Investigator will restrict the dissemination of BIPI Confidential Information to those persons participating in the Trial on behalf of Institution and/or Investigator who have a need to know and will ensure that each such person is aware of the obligation of confidentiality required by this Agreement and shall abide by confidentiality obligations at least as onerous as those set forth in this Agreement. Institution will and will cause Investigator and Institution's employees, representatives, contractors and agents participating in the Trial to comply with the terms of this Agreement and use at least the same care and discretion in maintaining the confidentiality of BIPI Confidential Information as it uses with its confidential information of like nature. This Section 7.2 shall be subject to Institution's right to publish as set forth in Section 9 and Institution's right to use Intellectual Property and Trial Results as set forth in Section 8.

Notwithstanding the immediately preceding paragraph, if Institution and/or Investigator are legally required by government order or subpoena or are otherwise required by law or regulation to disclose BIPI Confidential Information, Institution will notify BIPI in writing no less than three (3) business days prior to making the required disclosure. In the event notification in writing is not possible three days prior to the required disclosure, then verbal notice may be given no later than three (3) business days prior to the required disclosure, to the extent that the Institution is given at least three (3) days' notice by such governmental or regulatory agency, followed by written notice at the earliest practicable time. Institution and/or Investigator will use reasonable efforts to give due consideration to BIPI's comments when crafting such disclosure, and such disclosure will contain only such BIPI Confidential Information as is required by applicable law. Nothing contained herein will prohibit Institution and/or Investigator from immediately disclosing results of the Trial relating to a particular Trial Subject to such Trial Subject or the attending physician of such Trial Subject to the extent necessary for the health care or safety of Trial Subjects, provided, however, that Institution and/or Investigator will notify BIPI in writing prior to, to the extent reasonably possible, and promptly after, making such a disclosure if such results of the Trial are still unpublished.

7.3 Breach Notification. Institution and/or Investigator will notify BIPI of any loss, compromise, or unauthorized use or disclosure of any part or all of BIPI's Confidential Information that comes to its attention. Such notice will be given as soon as possible and in keeping with reasonable notification practices from the day that Institution and/or Investigator knew of the loss, compromise, or unauthorized use or disclosure. Notice will be given in writing, to the BIPI Associate Director, Compliance at the address set forth in Article 21. For purposes of this

Agreement, (i) unauthorized use means the sharing, employment, application, utilization, examination or analysis of any BIPI Confidential Information not authorized under this Agreement, and (ii) unauthorized disclosure means the release, transfer, provision of, access to or divulging in any other manner, any BIPI Confidential Information, except as expressly permitted hereunder. Use or disclosure of BIPI Confidential Information is unauthorized if it (a) violates the provisions of this Agreement or the Individual Clinical Trial Agreement, or (b) constitutes a breach of any applicable U.S. federal or state statute, regulation or guidance, or breach notification laws.

7.4 Communication of BIPI Confidential Information via Internet Mail. If BIPI Confidential Information is communicated via internet mail, the parties will use Internet mail encryption technology. For direct communication between all of the parties to this Agreement and to the Individual Clinical Trial Agreement, BIPI provides a suitable technology free of charge at http://guides.boehringer-ingelheim.com, if which Institution may use at its option in lieu of its own encryption technology. Without limiting the foregoing, any failure by BIPI to use such Internet mail encryption technology in its communication of any BIPI Confidential Information will not affect the confidential and proprietary nature of such information. Rather, such information will continue to be BIPI Confidential Information and subject to the restrictions of this entire Article 7.

7.5 Return or Destruction of BIPI Confidential Information. Following the termination of this Agreement or an Individual Clinical Trial Agreement, as applicable, for any reason or completion of the Trial by Institution and Investigator, and upon BIPI's written request, Institution and Investigator will promptly destroy or return to BIPI any and all BIPI Confidential Information for all Trials or for the specific Trial as applicable, except for one (1) copy which might be retained by Institution in its archives for the sole purpose of monitoring its compliance with this Agreement. Additionally, Institution may retain copies of all Trial Results, inventions, work product, and all other information developed or generated by Institution, Investigator or any other person working on behalf of Institution pursuant to the conduct of this Trial under this Agreement for use by Institution in accordance with Sections 8.1(b) and 9.2. Notwithstanding the foregoing, Institution may retain business documents generated by Institution and one copy of BIPI Confidential Information to comply with applicable record retention requirements or procedures, but only to the extent required by applicable statute or regulation or other governmental requirement, and all such BIPI Confidential Information will continue to be subject to the confidentiality provisions of this Agreement.

7.6 Benchmarking. Notwithstanding anything to the contrary herein, BIPI may disclose, in confidence, budget information related to this Agreement and/or an Individual Clinical Trial Agreement to third-parties retained by BIPI to perform services in furtherance of BIPI's internal business operations. Such third-party services may include, but will not be limited to, utilization of metadata from the Clinical Trial Budget to benchmarking the fair market value of clinical trial work to be done by Institution hereunder. Any such disclosure will not identify or name the Institution or Investigator or any other information linking to the Institution.

8. PROPERTY RIGHTS

8.1 Intellectual Property.

(a) Definition of Intellectual Property. As used herein, "Intellectual Property" will mean all rights, title and interest in and to the BI Investigational Product and all data, technical information, inventions, discoveries, developments, improvements, enhancements, software, know-how, methods, techniques, formulae, processes, or other proprietary ideas (whether or not patentable or registrable under patent, copyright or similar laws) and all intellectual property rights therein, that are related to any Trial Drug or its uses (including, without limitation, the BI Investigational Product or its uses), the Trial or the Protocol, provided by BIPI to Institution under this Agreement, and that (i) are otherwise derived, conceived, discovered, developed or reduced to practice as a result of (1) Institution's or Investigator's performance of any services under or pursuant to this Agreement or the Individual Clinical Trial Agreement in the performance of a Trial, including but not limited to as a result of any review or other use of Trial Results (as defined in Section 8.2 below) as part of the performance or analysis of the Trial; or (2) any

deviation from the Trial Protocol or (ii) otherwise incorporates or is derived from BI Confidential Information provided by BIPI to Institution under this Agreement, all of the foregoing whether generated or developed by Institution, Investigator or Institution's agents, employees or contractors, either solely or jointly, in the conduct of the Trial. Intellectual Property excludes Institution Records (as defined in Section 8.3 below), Source Documents (as used in Section 8.3 below), original medical records or any other information that is required by law or regulation to be retained by Institution.

(b) Ownership of Intellectual Property. Institution acknowledges and agrees that all Intellectual Property is the property of BIPI and that all Intellectual Property will be considered BIPI Confidential Information. Institution hereby assigns to BIPI all right, title and interest in any Intellectual Property that may be created. BIPI will have the sole and exclusive right to obtain, file and prosecute in its own name or in another entity's name, and at its own discretion and expense, applications for patents on any Intellectual Property. Upon request and at the expense of BIPI, Institution and/or Investigator will use commercially reasonable efforts to assist BIPI in BIPI's efforts in securing and enforcing BIPI's rights in the Intellectual Property including any copyrights, (not including academic publications or other scholarly work by the Institution and/or Investigator made pursuant to Section 9.2), patents or other intellectual property rights, including disclosure to BIPI of all relevant or pertinent information and data with respect to such Intellectual Property, the execution of all reasonable applications, specifications, oaths, assignments and all other reasonable instruments necessary in order to apply for and obtain such rights and in order to assign and convey to BIPI or another entity designated by BIPI, or their successors and assigns the sole and exclusive rights, title and interest in and to such Intellectual Property including any copyrights, (not including academic publications or other scholarly work by the Institution and/or Investigator made pursuant to Section 9.2), patents or other intellectual property rights. The obligation of Institution and Investigator to assist BIPI as described herein will continue beyond the termination of this Agreement, the termination of an Individual Clinical Trial Agreement, or completion of the Trial by Institution and Investigator and will be binding upon their respective successors, assigns, and other legal representatives. Institution will ensure that all persons working on the Trial have previously assigned to Institution to BIPI all their respective rights to any Intellectual Property (not including academic publications or other scholarly work by the Institution and/or Investigator made pursuant to Section 9.2). At all times, BIPI will have the exclusive right to use, assign, license or transfer ownership of any Intellectual Property in any way deemed by it to be necessary or desirable without payment of any compensation to Institution for such Intellectual Property, provided, any such assignments, licenses or transfers of ownership shall not limit Institution's rights under this Section 8.1(b). Notwithstanding the foregoing, Institution will be permitted to use any Intellectual Property generated and contributed by Institution for its internal and non-commercial research, teaching, patient care purposes. Institution may publish the Trial Results generated and contributed by Institution in accordance with Section 9.2 and such resulting publications shall not be deemed BIPI Intellectual Property.

(c) Federal Technology Transfer Act. Institution represent and certifies that any and all Intellectual Property generated or developed by Institution in connection with the Trial are not subject to restrictions imposed by the Federal Technology Transfer Act of 1986, Pub. L. No. 99-502, October 20, 1986, which was amended by Pub. L. No. 104-113, March 7, 1996, and Pub. L. No. 106-404, November 1, 2000.

8.2 Trial Results. Any and all information, documents, reports, data, results or other information generated or developed as a result of or in connection with the Trial, and all copies thereof, (excluding Institution Records defined below), collectively, the "Trial Results", will be the property of BIPI and may be (i) used by BIPI or an entity designated by BIPI for any lawful purpose, including, without limitation, in connection with any of its research, development, marketing or promotional activities; (ii) disclosed by BIPI or an entity designated by BIPI as required by applicable law or regulation, including without limitation, disclosure on www.clinicaltrials.gov; and (iii) disclosed by BIPI or an entity designated by BIPI to third parties, including, without limitation, other clinical investigators, consultants, the FDA, and other federal, state and/or local regulatory agencies without further obligation or liability to Institution or Investigator. Notwithstanding anything to the contrary herein, Institution shall have the right to use Trial

Results contributed and/or generated by Institution for Institution's own internal, non-commercial educational, training or research purposes, for patient care purposes, and for publication purposes in accordance with Section 9.2.

8.3 Source Documents and Medical Records. Notwithstanding anything to the contrary, the parties acknowledge and agree that the individual medical records of Trial Subjects, as well as Source Documents generated by Institution as defined in the Good Clinical Practice: Consolidated Guidelines published by the Food and Drug Administration, shall not be deemed Intellectual Property, Trial Results or BIPI Confidential Information and are the exclusive property of Institution. Without limiting the generality of the foregoing laboratory notebooks, Protected Health Information (as such term is defined by HIPAA), Institution's business records, regulatory and compliance documents, research notebooks, Source Documents, original medical records or any other information that is required by law or regulation to be retained by Institution, (collectively referred to as "Institution Records") shall be considered the exclusive property of Institution. Notwithstanding the foregoing, BIPI shall have the right to inspect, audit, and/or copy the medical records and Source Documents subject to and in accordance with Section 11.1 and the informed consent and HIPAA authorization.

8.4 Specimens. Upon written request which may be outlined in the specific Protocol, (a) Institution will provide BIPI with biological materials and samples, such as blood or tissue, collected from a Trial Subject pursuant to the Protocol (such materials and samples "Specimens") and (b) BIPI shall have the right to possess, control, retain, store, and use the Specimens only for purposes of or in connection with the Trial, including for the generation, analysis or confirmation of Trial Results, or otherwise to prepare for a regulatory submission for purposes of or incorporating the Trial Results (collectively, "Specimen Analysis"), but (a) and (b) shall apply only to the extent permitted by the IRB, the IRB approved Protocol and informed consent document(s)/authorization signed by the Trial Subjects and only in accordance with applicable laws and regulations. BIPI will promptly provide Institution with a copy of all data generated from Specimens. For clarity, Institution shall be the owner of Specimens.

8.5 Advertising Materials. Usage rights in photography/images/fonts utilized in materials provided by BIPI to Institution and/or Investigator hereunder that are then provided to patients pursuant to recruitment activities under the Individual Clinical Trial Agreement including all materials, documents, presentations, reports, information, data, results, analyses, summaries, and suggestions of every kind and description supplied to Institution and/or Investigator by BIPI hereunder shall be the sole and exclusive property of BIPI. All such BIPI property which Institution and/or Investigator may have in its possession and control shall be returned to BIPI upon request.

8.6 Names and Trademarks. No party will use the other party's/parties' name(s) or trademark(s) in any advertising or other form of publicity without prior written consent of the other party/parties, except as otherwise required by law. BIPI may use the name of Institution and/or Investigator, and other identifying information as may be required by law, regulation, guideline or other legal requirement in any publication, submission to any regulatory authority, reports or disclosures made pursuant to Section 4.3(L), and/or disclosures required by applicable law or regulation, including without limitation, disclosures on www.clinicaltrials.gov. For purpose of clarity, nothing in the foregoing sentence shall be construed as giving BIPI permission to use the name of Institution and/or Investigator or other identifying information in press releases or other forms of publicity or marketing except to the extent required by law or regulation, without the prior written consent of Institution's Office of External Communications. Notwithstanding the foregoing, Institution may (i) acknowledge the existence of the Agreement; (ii) the name of BIPI; (iii) the Protocol title; and (iv) the amount of funding provided by BIPI in support of this Trial as necessary to comply with regulatory, academic and state reporting requirements. Additionally, notwithstanding the foregoing, Institution may use the name of BIPI in any academic publication in accordance with Section 9.

9. PUBLICATION

9.1 Publication by BIPI. Without limiting Article 8, BIPI will have unrestricted publication rights with respect to Trial Results and may disclose such Trial Results to third parties for publication.

9.2 Publication by Investigator. BIPI acknowledges Institution has the right to publish the Trial Results that Institution contributes and generates as a result of the Trial with due regard to the protection of BIPI Confidential Information and consistent with the below paragraph regarding a joint multi-investigator publication. Institution must submit any proposed publication to BIPI at least forty-five (45) days before submission for publication, and BIPI will have the right to review and comment upon the publication in order to protect BIPI Confidential Information provided however that nothing herein shall be interpreted as to require the Investigator or Institution to delete Trial Results generated and contributed by Institution. Prior to submitting or releasing such publication, Institution will delete information identified by BIPI as BIPI Confidential Information provided, however, nothing herein shall be construed as requiring Institution to delete any Trial Results or data of the Trial generated or contributed by Institution. Upon BIPI's request, publication will be delayed up to forty-five (45) additional days to enable BIPI to secure adequate intellectual property protection.

Institution acknowledges that if the Trial is part of a multicenter study, BIPI anticipates publishing an independent, joint multi-investigator publication, with authors to be named by BIPI in its sole discretion, but always in accordance with Section 9.3 below. Therefore, Institution or Investigator will not publish independently the results of the Trial before the publication of the joint, multi-investigator publication. Without limiting the foregoing, if there is no joint multicenter publication within twelve (12) months after completion, termination or abandonment of the Trial at all sites, then Institution is free to publish the results that Institution contributes and generates as a result of the Trial, subject to review and comment as set forth in the preceding paragraph.

Institution acknowledges and agrees that neither Institution, Investigator, nor any employee, contractor, or agent of Institution has any publication rights with respect to any non-publicly available aspects of the Trial, Protocol, BI Investigational Product, or any other BIPI Confidential Information except as specifically set forth herein.

9.3 International Committee of Medical Journal Editors. BIPI will adhere to the International Committee of Medical Journal Editors ("ICMJE") requirement on clinical trial registration and represents that the Trial will be registered according to ICMJE applicable requirements and all applicable federal and state laws regarding clinical trial registration prior to the recruitment of the first Trial Subject. BIPI agrees to provide proof of such registration to Institution upon written request. For all publications relating to the Trial or including any Trial data, BIPI, Institution and Investigator will comply with all ethical standards concerning publications and authorship, including Section II of the Uniform Requirements for Manuscripts Submitted to Biomedical Journals titled "Ethical Considerations in the Conduct and Reporting of Research" (found at http://www.icmje.org), as established by ICMJE.

10. TRIAL DOCUMENTS

10.1 Trial Document Requirements. Institution agrees to and shall cause Investigator to accurately maintain, organize, keep current and complete all essential documents, including, but not limited to, written or electronic records, copies of CRFs and eCRFs, accounts, notes, reports and data collected or performed as part of the Trial under this Agreement and the Individual Clinical Trial Agreement, including patient care medical records and progress reports for each Trial Subject, and any other records or reports required by applicable law, in full compliance with the Protocol and to maintain such documents in a secure area. Institution and/or Investigator will provide to BIPI CRFs or eCRF's for each Trial Subject and such other reports as required by and in accordance with Section 3.8.

10.2 Document Retention. Institution will maintain and preserve all essential documents and any other original records and data related to or generated as part of the Trial in accordance with FDA guidelines, ICH GCP Guidelines, any applicable statutes and regulations, and any and all other applicable record retention requirements. Without limiting the foregoing, Institution will archive all essential documents of the Trial in their original format for a minimum of fifteen (15) years following the later of the date of (i) termination of the Individual Clinical Trial Agreement (including termination of such Individual Clinical Trial Agreement as a result of the termination of this Agreement) or

(ii) completion of the Trial by Institution and Investigator; provided, however, that Institution is obligated to archive such documents beyond the time period required by applicable law only to the extent that Institution is compensated for such archiving in the applicable Clinical Trial Budget. Institution and Investigator will obtain prior written approval from BIPI prior to destroying any essential documents of the Trial. Institution and Investigator will make all documents available for review, audit and inspection in accordance with Article 11 hereof.

11. MONITORING, AUDITS AND INSPECTION

11.1 Access. BIPI, its agents and, when applicable, IRB and regulatory authorities, including foreign regulatory authorities, may, at any time during normal administrative business hours and mutually agreeable times with respect to BIPI or its agents' rights under this provision, (i) inspect any site where the Trial is being carried out; (ii) monitor and/or audit the conduct of the Trial; (iii) inspect and audit any and all Trial documents, Source Documents, medical records, work product, and required licenses, certificates and accreditations, provided that any such inspection or auditing of PHI, as defined herein, and BIPI's subsequent use of the PHI shall be made in compliance with the informed consent and HIPAA authorization form; or (iv) to the extent reasonably possible, interview any Institution person involved in the conduct of the Trial. Additionally, during the term of the Individual Clinical Trial Agreement and for a period of twenty-four (24) months after completion of the Trial, BIPI shall be entitled to inspect Institution's financial accounts directly related to the Trial. Institution will, and will cause its personnel to, reasonably cooperate with any of the foregoing activities and will provide timely access to requested documentation and facilities. Without limiting the foregoing, if Institution stores and retains its records in an electronic records system, Institution may allow access to Trial documents through such electronic records system in order to comply with this Section 11.1. In the event it is not possible, after the exercise of reasonable efforts, to allow access to Trial documents in Institution's electronic records system without jeopardizing the privacy rights of other patients of Institution, or violating any applicable laws or regulations, Institution shall ensure that Investigator will print and provide to the requestor certified hardcopies of all relevant documents and information. Institution will maintain, create, modify, archive, retrieve and transmit, and make available for inspection by regulatory authorities, all electronic Trial records in compliance with applicable statutes and regulations. In addition, Institution will ensure that Investigator will make available information as to the progress of the Trial in accordance with the Protocol or as otherwise reasonably requested by BIPI in writing, and will make reports as agreed between Investigator and BIPI. Institution will and will ensure that Investigator will reasonably cooperate in resolving any identified findings and/or discrepancies. In the event BIPI accesses Institution's premises or electronic records system pursuant to this Section, BIPI will comply with Institution's reasonable measures for purposes of confidentiality, safety, and security, and will be subject to Institution's reasonable premises rules that are applicable to all persons at Institution's facilities. Should BIPI utilize one or more third party(s) in exercising its rights in this paragraph, BIPI agrees that such party(s) shall be subject to an obligation of confidentiality consistent with the obligations of confidentiality required by BIPI hereunder and such third party(s) shall be subject to any and all conditions upon BIPI's rights that are set forth in this Section. If BIPI obtains, learns of, comes in contact with, or otherwise has access to any PHI, as defined herein, BIPI will keep such information confidential and will comply with all applicable laws regarding the confidentiality of such information and BIPI will not use or disclose such patient health and medical information in a manner that would violate any applicable law (including the HIPAA Privacy Regulations) if such use or disclosure were made by Institution.

11.2 FDA or Other Governmental or Regulatory Authority Inspections. Institution and/or Investigator will notify BIPI promptly by telephone or facsimile if, in connection with the Trial or in connection with any matter that may affect Institution's or Investigator's performance of the Trial, the FDA or any other governmental or regulatory authority requests permission to or does inspect Institution's and/or Investigator's facilities or research records. In accordance with applicable law, Institution will and will ensure that Investigator will provide in writing to BIPI copies of all relevant materials, correspondence, statements, forms and records which Institution and/or Investigator receives, obtains or generates pursuant to any such inspection related to the Trial.

12. INDEMNIFICATION

12.1 BIPI Indemnification. BIPI will indemnify, defend and hold harmless Institution, The University of Texas System, and their Regents, officers, agents and employees (collectively "Institution Indemnitees") from any liability, loss, costs, or damages (collectively "Liabilities") they may suffer as the result of claims, demands or judgments against them to the extent arising from the BI Investigational Product, the use by BIPI of the results of the Study or the activities to be carried out by BIPI pursuant to this Agreement and the Individual Clinical Trial Agreement, and any procedures or activities to be carried out solely for the purpose of the Protocol, provided, however, that BIPI will not be responsible for any Liabilities arising from any injuries or damages to the extent resulting from (i) the negligence, fault, intentional misconduct, errors or omissions of any Institution Indemnitee; (ii) research activities conducted by any Institution Indemnitee contrary to or outside the scope of the Protocol, this Agreement or the Individual Clinical Trial Agreement provided, however, that Emergency Deviations made in accordance with Section 3.9 or Non-Emergency Additional Treatment approved by BIPI pursuant to Section 3.10 shall not be deemed contrary to or outside the scope of the Protocol, this Agreement or the Individual Clinical Trial Agreement for this Section 12.1(ii); (iii) actions by any Institution Indemnitee in violation of applicable laws, regulations, ICH GCP Guidelines, or in violation of this Agreement, the Individual Clinical Trial Agreement or any reasonable written instruction provided by BIPI relative to the conduct of the Trial; or (iv) unauthorized warranties by any Institution Indemnitee relating to the BI Investigational Product, any other Trial Drug or the Trial.

BIPI agrees to provide a diligent defense against any claims brought or actions filed against Institution Indemnitees with respect to the subject of the indemnity contained in this Section whether such claims or actions are rightfully or wrongfully filed.

This provision 12.1 is subject to the statutory duties of the Texas Attorney General.

12.2 Institution Indemnification. To the extent authorized by the Constitution and laws of the State of Texas, Institution will indemnify, defend and hold harmless BIPI, its officers, agents and employees (collectively "BIPI Indemnitees") from any Liabilities they may suffer as a result of claims, demands or judgments against them to the extent arising directly from any injuries or damages that are a result of (i) the negligence, fault, intentional misconduct, errors or omissions of any Institution Indemnitee in connection with the Trial; (ii) research activities conducted by any Institution Indemnitee contrary to or outside the scope of the Protocol, this Agreement or the Individual Clinical Trial Agreement provided, however, that Emergency Deviations made in accordance with Section 3.9 or Non-Emergency Additional Treatment approved by BIPI pursuant to Section 3.10 shall not be deemed contrary to or outside the scope of the Protocol, this Agreement or the Individual Clinical Trial Agreement for this section 12.2(ii); (iii) actions by any Institution Indemnitee in violation of applicable laws, regulations, ICH GCP Guidelines, or in violation of this Agreement, the Individual Clinical Trial Agreement or any reasonable written instruction provided by BIPI relative to the conduct of the Trial; or (iv) unauthorized warranties by any Institution Indemnitee relating to the BI Investigational Product, any other Trial Drug or the Trial, provided, however, that Institution will not be responsible for any Liabilities arising from any injuries or damages to the extent resulting from (i) the negligence, fault, intentional misconduct, errors or omissions of any BIPI Indemnitee (ii) research activities properly conducted by any Institution Indemnitee in accordance with the Protocol; (iii) actions by any BIPI Indemnitee in violation of applicable laws, regulations, ICH GCP Guidelines, or in violation of this Agreement or the Individual Clinical Trial Agreement.

Institution agrees to provide a diligent defense against any claims brought or actions filed against BIPI Indemnitees with respect to the subject contained in this Section whether such claims or actions are rightfully or wrongfully brought or filed.

12.3 Conditions of Indemnity. Either party (herein referred to as the "Indemnified Party") wishing to be indemnified by the other will:

(a) promptly after receipt of notice of any complaint or the commencement of any action, suit or proceeding giving rise to the right of indemnification, notify the other party thereof in writing of all the particulars known to the Indemnified Party and enclose a copy of all papers served;

(b) permit the other party to retain counsel of its choosing to represent the Indemnified Party (but in the event that the party does not elect to choose counsel to represent the Indemnified Party, the Indemnified Party may select its own counsel, and the fees and costs of such counsel will be borne by the other party); and

(c) allow the other party to retain control of such action, suit or proceeding, including the right to make any settlement, provided that the other party will not make any settlement which (a) admits fault on the part of the Indemnified Party or could reasonably be expected to have a negative effect on the reputation of the Indemnified Party without the prior written consent of the Indemnified Party, (b) shall require the Indemnified Party to contribute to the settlement or to admit fault, or (c) shall require the Indemnified Party to change its operations or business practices.

(d) This Section 12.3 is subject to the statutory duties of the Texas Attorney General.

13. INSURANCE

Institution has and will maintain in force during the term of this Agreement adequate insurance or self-insurance to cover its indemnification obligations hereunder. Institution, as a member institution of System, is an agency of the State of Texas and is self-insured pursuant to The University of Texas System Professional Medical Liability Benefit Plan, under the authority of Section 59, Texas Education Code. Furthermore, as a member institution of The University of Texas System and an agency of the State of Texas, Institution will address issues of general liability in accordance with the Texas Civil Practice and Remedies Code, Chapter 101 (the Texas Tort Claims Act. Institution will maintain Workers' Compensation insurance in the amounts required by state and federal law.

Throughout the term of this Agreement, BIPI shall maintain a self insurance policy at levels sufficient to support its obligations assumed herein. BIPI represents that it is self insured and, upon request, will deliver certificate(s) evidencing such coverage

14. TRIAL SUBJECT INJURY

BIPI will reimburse Institution for any reasonable medical expenses incurred in providing a Trial Subject with treatment which the Institution provides to the Trial Subject pursuant to the informed consent document approved by BIPI and the IRB and signed by the Trial Subject, provided that:

a) The injury for which medical treatment is provided was sustained as a direct result of the Trial Drug or any Trial procedure performed in accordance with the Protocol;

b) The injury is not associated with the Trial Subject's underlying disease or condition or with the expected complications of the usual treatment for such underlying disease or condition.

BIPI will reimburse Institution for claims for expenses described in this Article 14 for Trial Subjects at a rate that will not exceed the reasonable, customary, and fair market amount comparable to that paid by private commercial insurers for such services. In the event medical treatment of a Trial Subject for an injury or illness described above is provided by a third-party medical provider, Institution will if necessary and in good faith, work with

BIPI and such third-party provider concerning BIPI's reimbursement to such third-party provider at the rate described in the preceding sentence or as otherwise agreed by BIPI.

Notwithstanding the foregoing, BIPI will not reimburse Institution for medical expenses described above to the extent that the injury was sustained as a result of (i) the negligence, fault, intentional misconduct, errors or omissions of any Institution Indemnitee; (ii) research activities conducted by any Institution Indemnitee contrary to or outside the scope of the Protocol or this Agreement provided, however, that Emergency Deviations made in accordance with Section 3.9 or Non-Emergency Additional Treatment approved by BIPI pursuant to Section 3.10 shall not be deemed contrary to or outside the scope of the Protocol or this Agreement for this Section 14; (iii) intentional actions by any Institution Indemnitee in violation of applicable laws, regulations, ICH GCP Guidelines, or in violation of this Agreement; or (iv) unauthorized warranties by any Institution Indemnitee to a Trial Subject relating to the BI Investigational Product, any other Trial Drug that is the subject of the Trial in which Trial Subject is enrolled or the Trial. Institution will use reasonable efforts to provide to BIPI sufficient documentation to review and process any Trial Subject injury reimbursements, provided, however, that any and all patient identifiers will be removed from any documentation submitted to BIPI.

14.1 MMSEA Reporting Obligations. Should BIPI have obligations under Section 111 of the Medicare, Medicaid, and SCHIP Extension Act of 2007 ("MMSEA"), BIPI may contact Institution for Trial information. Institution through its IRB or other designated representatives will reasonably cooperate with BIPI to assist BIPI in meeting BIPI's MMSEA notification and reporting obligations by discussing BIPI's requests for any Trial Subject PHI information to BIPI and/or BIPI's designated agents or subcontractors, subject to and to the extent permitted by the applicable informed consent and HIPAA authorization and the IRB ("MMSEA Information") solely to the extent that such MMSEA Information is required to meet such MMSEA notification and reporting obligations. In connection with a Trial, Institution further agrees to otherwise reasonably cooperate, through its IRB or other designated representatives, with BIPI and its designated agents and subcontractors if and to the extent necessary for BIPI to meet its MMSEA notification and reporting obligations. BIPI will not use any MMSEA Information for any purpose other than for BIPI's MMSEA reporting requirements. BIPI shall implement appropriate data safeguards, policies and procedures to ensure the confidentiality and security of the MMSEA Information. BIPI shall ensure that any agents, including subcontractors, to whom it provides the MMSEA Information, or to whom BIPI directs Institution to provide such MMSEA Information, agree to the same restrictions and conditions set forth in this Agreement, and BIPI shall remain responsible to Institution for the actions or omissions of such agents and subcontractors with respect to such MMSEA Information in breach of these restrictions and conditions.

15. FINANCIAL DISCLOSURE

In connection with a Trial, Institution will and will ensure that Investigator cooperates with BIPI in providing information as may be reasonably required by BIPI to comply with 21 CFR Part 54, Financial Disclosure by Clinical Investigators. Without limiting the foregoing, Investigator agrees that s/he and any sub-investigators, including, to the extent required by 21 CFR Part 54, the spouse and each dependent child of Investigator and sub investigators will provide sufficient and accurate financial information regarding interests and arrangements to enable BIPI to submit complete and accurate required certification or disclosure statements and comply with 21 CFR Part 54. At a minimum, sufficient and accurate financial information must be provided through the completion of a BIPI Financial Disclosure Questionnaire (i) prior to Trial initiation and as new investigators/sub-investigators are added to the Trial staff list; and (ii) upon any change in reportable information during the course of the Trial and for one (1) year following completion of the Trial. BIPI may seek forwarding addresses for Investigator and all sub-investigators who are no longer working on the Trial. If Investigator or any sub-investigators refuse to disclose their interests, such individuals will not be allowed to participate in the Trial. Investigator acknowledges that the Financial Disclosure Questionnaire may be included in a regulatory submission in the United States and that the FDA reserves the right to make the information public if it feels that it is in the public's best interest.

16. FORCE MAJEURE

Neither BIPI, Institution nor Investigator will be liable for any failure to perform as required by this Agreement or the Individual Clinical Trial Agreement to the extent such failure to perform is beyond such party's control by reason of any of the following: labor disturbances or disputes, failure to obtain required government approval, civil disorder, acts of aggression, acts of God or acts of terrorism.

17. ASSIGNMENTS

Institution will not assign this Agreement (or any portion hereof) or any Individual Clinical Trial Agreement (or any portion thereof) to another party without the prior written consent of BIPI. Any assignments without such written consent will be void. BIPI may assign this Agreement and/or the Individual Clinical Trial Agreement, at its discretion, to any parent, subsidiary or other Affiliate of BIPI.

18. SEVERABILITY AND ENFORCEABILITY

In the event that a court of competent jurisdiction holds any provision of this Agreement and/or an Individual Clinical Trial Agreement to be invalid, it will have no effect on the remaining provisions of the applicable agreement(s), and such agreement(s) will continue in full force and effect. Should any provision of this Agreement and/or the Individual Clinical Trial Agreement be unenforceable as between the parties, such unenforceability will not affect the enforceability of the other provisions of this Agreement or the Individual Clinical Trial Agreement.

19. HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT

Institution will and will ensure that Investigator will comply with all applicable federal, state and local laws and regulations relating to the privacy of subject health information, including, but not limited to, the Standards for Individually Identifiable Health Information, 45 CFR Parts 160 and 164 (the "HIPAA Privacy Regulation") and the Department of Health and Human Services Health Information Technology for Economic and Clinical Health Act of 2009, as amended (HITECH) and all state consumer privacy laws. It is understood and agreed that Institution and Investigator will not use or disclose Protected Health Information ("PHI"), as defined in the HIPAA Privacy Regulation, for purposes other than treatment, payment or health care operations without first obtaining authorization from the individual concerned. In connection with the Trial, Institution and/or Investigator will collect PHI from participating Trial Subjects. Pursuant to the HIPAA Privacy Regulations, Institution and Investigator will, to the extent permitted by Institution's IRB, obtain authorization from the Trial Subject to permit disclosure and use of PHI to BIPI and/or BIPI's agents, for purposes of conducting and overseeing the Trial, in accordance with the HIPAA Privacy Regulation. Institution and Investigator will permit BIPI and/or its designated representative(s) to review and approve its authorization forms prior to commencement of the Trial. Further, Institution and Investigator will permit BIPI and/or its authorized representative(s) to review such executed authorizations upon request. Such review will be subject to BIPI's audit rights in Section 11.1. Institution understands and will ensure that Investigator understands and agrees that any person who does not provide such authorization will be unable to enroll in the Trial.

20. PROVISION OF EQUIPMENT

If BIPI or an Affiliate of BIPI supplies Institution and/or Investigator with a notebook computer (the "Computer") for use in the Trial, an agent of BIPI will work with Institution and/or Investigator to determine a suitable location for the Computer and to determine the appropriate mode of data connection. If BIPI or an Affiliate of BIPI provides any other equipment (the "Equipment") for use in connection with performance of services in the Trial, Institution and/or Investigator will determine a suitable location for the Equipment. Institution and/or Investigator will store the Computer and any Equipment in a secure place when not in use and protect it from theft and/or damage. Institution will reimburse BIPI for any damage to or loss or theft of the Computer or Equipment caused by Institution's intentional

misconduct. Institution and Investigator will use the Computer and any Equipment only in connection with the services specified in the Protocol with respect to Trial Subjects. At the conclusion of the Trial, Institution and Investigator will return the Computer, in good working condition, to BIPI or its Affiliate and to either return, in good working condition, to BIPI or its Affiliate or destroy any Equipment supplied under this Agreement, as directed in writing by BIPI. Reasonable costs for returning the Computer and Equipment will be borne by BIPI or its Affiliate. Any additional information regarding the Remote Data Capture ("RDC") terms and conditions is supplied in the Protocol and RDC User Guide.

21. MISCELLANEOUS PROVISIONS

21.1 Independent Contractors. In the performance of services hereunder and under the Individual Clinical Trial Agreement, Institution and Investigator are, and will be deemed to be, independent contractors with respect to BIPI. Nothing in this Agreement or the Individual Clinical Trial Agreement is intended nor will be construed to create a partnership, employer-employee or joint venture relationship between BIPI and either Institution and/or Investigator. No party to this Agreement or the Individual Clinical Trial Agreement is authorized or empowered to act as agent for any other party, and no party will have any authority to make any statements, representation or commitments of any kind or to take any action on behalf of or binding upon another party. No party will be bound by the acts or conduct of another party, except as expressly provided herein, or as authorized in writing by the party to be bound.

21.2 Survival. The terms and conditions of the Sections titled Publicity and Advertising; Responsibility for BI Investigational Product; Adverse Event Reporting; Compliance, Documents, Case Report Forms, and Final Data Submission; Hold-Back, Final Accounting and Payment; Reporting of Payments; Effects of Termination; MMSEA Reporting Obligations; and the entire Articles titled Confidential Information; Property Rights; Publication; Trial Documents; Monitoring, Audits, and Inspection; Indemnification; Insurance; and Financial Disclosure and any other provisions that are intended to survive termination or completion of the Trial will survive termination or completion of this Agreement.

21.3 Interpretation. The article and section headings contained herein and in the Individual Clinical Trial Agreement are for convenience of reference only and, except as listed in Section 21.2 herein, do not constitute part of the agreements and are not intended to define, limit or describe the scope or intent of any provision of the agreements.

21.4 No Third Party Beneficiary. Except as expressly provided in this Agreement or in the Individual Clinical Trial Agreement, including for example any "entity designated by BIPI" in Section 8.2 of this Agreement, no person or entity that is not a party to the agreements will be a third party beneficiary of any rights or obligations hereunder or be entitled to enforce any of said rights or obligations.

21.5 Course of Dealing. The failure of any party to enforce at any time any of the provisions of this Agreement or the Individual Clinical Trail Agreement will in no way be construed to be a waiver of any such provision or to affect the validity of this such agreement, or any part thereof, or the right of any party thereafter to enforce each and every such provision. No waiver of any breach of this Agreement or the Individual Clinical Trial Agreement will be held to be a waiver of any other or subsequent breach.

21.6 Drafting. BIPI has drafted this Agreement and the Individual Clinical Trial Agreement solely as a matter of convenience for the parties hereto. The parties hereto have carefully reviewed and negotiated the terms of this Agreement and the Individual Clinical Trial Agreement and, accordingly, any drafting errors, ambiguities or inconsistencies will not be interpreted against BIPI.

21.7 Notices. All notices required or permitted to be given by one party to the other(s) under this Agreement or the Individual Clinical Trial Agreement will be sufficient if sent by certified mail, return receipt requested, or via nationally recognized overnight carrier with all freight charges prepaid and addressed as follows (or as subsequently noticed to the other party/parties) and as stated in the Individual Clinical Trial Agreement:

If to BIPI:	Boehringer Ingelheim Pharmaceuticals, Inc. 900 Ridgebury Road/P.O. Box 368 Ridgefield, CT 06877-0368 Attention: Executive Director, Clinical Support & Information Management Telephone: (203) 791-6161 Facsimile: (203) 837-5815
with a copy to:	Attention: General Counsel Address same as above
Also with a copy to:	Attention: Address same as above
If to Institution:	See Appendix A for the name and address of an administrative contact for each Institution

With a copy to:	The University of Texas System Office of General Counsel 201 West 7th Street Austin, TX 78701 ATTN: OGC Intellectual Property Assistant General Counsel and IP Legal Expert

21.8 Entire Agreement; Binding Effect; This Agreement, Appendix, and the Exhibit(s) contained herein, and each respective Individual Clinical Trial Agreements, including all exhibits thereto, contain the entire and final agreement among the parties hereto with respect to the Trial and supersedes all prior agreements, whether written or oral, with respect thereto. No provision of this Agreement or the Individual Clinical Trial Agreement may be modified, amended or waived in any manner whatsoever other than by a supplemental writing signed by the parties thereto or their respective successors in interest. This Agreement and each Individual Clinical Trial Agreement will be binding upon and inure to the benefit of the parties and their respective successors, assigns, heirs, executors and legal representatives.

21.9 State Agency Language. Institution is an agency of the State of Texas and under the Constitution and the laws of the State of Texas possesses certain rights and privileges, is subject to certain limitations and restrictions, and only has such authority as is granted to it under the Constitution and laws of the State of Texas. Notwithstanding any provision hereof, nothing in this Agreement is intended to be, nor will it be construed to be, a waiver of the sovereign immunity of the State of Texas or a prospective waiver or restriction of any of the rights, remedies, claims, and privileges of the State of Texas. Moreover, notwithstanding the generality or specificity of any provision hereof, the provisions of this Agreement as they pertain to Institution are enforceable only to the extent authorized by the Constitution and laws of the State of Texas; accordingly, to the extent any provision hereof conflicts with the Constitution or laws of the State of Texas or exceeds the right, power or authority of Institution to agree to such provision, then that provision will not be enforceable against Institution or the State of Texas.

21.10 Applicable Law. This Agreement is subject to, and the parties agree to comply with, all applicable local, state, federal, national and international laws, statutes, rules and regulations. Any provision of any law, statute, rule or regulation that invalidates any provision of this Agreement, that is inconsistent with any provision of this Agreement, or that would cause one or any of the parties hereto to be in violation of law will be deemed to have superseded the terms of this Agreement. The parties, however, will use all reasonable endeavors to accommodate the terms and intent of this Agreement to the greatest extent possible consistent with the requirements of the law and will negotiate in good faith toward amendment of this Agreement in such respect. If the parties cannot reach agreement on an appropriate amendment, then this Agreement may be immediately terminated by either party.

21.11 Conflict. In the event there is a discrepancy between this Agreement or the Individual Clinical Trial Agreement and the Protocol, the Protocol will govern with respect to medical and scientific issues and to Trial conduct, and this Agreement and/or the Individual Clinical Trial Agreement will govern with respect to all other issues. In the event there is a conflict between this Agreement and any Individual Clinical Trial Agreement, this Agreement shall control.

21.12 Signature. The parties may execute this Agreement in two or more counterparts which shall, in the aggregate, be signed by all the parties; each counterpart shall be deemed an original instrument as against any party who has signed such counterpart. Additionally, the parties may execute this Agreement by exchange of signatures sent by facsimile transmission or electronic transmission, including electronically scanned (i.e., PDF). Once signed by all parties, this Agreement shall become effective and binding, and such complete facsimile or electronic copy shall be treated the same as an original for all purposes under this Agreement.

SIGNATURE PAGE TO FOLLOW

IN WITNESS WHEREOF, the parties have executed this Agreement by their duly authorized officers or representatives.

BOEHRINGER INGELHEIM PHARMACEUTICALS, INC.

By: Jeanne T. Varrone MD

Name and Title: Jeanne T. Varrone, M.D.
Vice President
Clinical Operations

Date: Jan 25 2016

THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT HOUSTON

Christopher Denman, MRA, CRA
Assistant Director, Contracts
Sponsored Projects Administration

Digitally signed by Christopher Denman
DN: postalCode=77030, ou=UTHEALTH NON-ESCROW, o=The University of Texas Health Science Center at Houston, street=7000 Fannin, st=Texas, l=Houston, c=US, cn=Christopher Denman, email=christopher.denman@uth.tmc.edu
Date: 2016.01.12 11:40:21 -06'00'

THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT SAN ANTONIO

By:

Name and Title:

Date:

IN WITNESS WHEREOF, the parties have executed this Agreement by their duly authorized officers or representatives.

BOEHRINGER INGELHEIM PHARMACEUTICALS, INC.

By: _____

Name and Title: _____

Date: _____

THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT HOUSTON

By: _____

Name and title: _____

Date: _____

THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT SAN ANTONIO

By: Chris G. Green

Chris G. Green, CPA

Name and Title: Director, Office of Sponsored Programs

Date: 1-13-16

THE UNIVERSITY OF TEXAS SOUTHWESTERN MEDICAL CENTER

By: Anglea R Charboneau Wishon

Name and Title: Anglea R. Charboneau Wishon, J.D., Vice President for Research Administration

Date: 1-11-2016

THE UNIVERSITY OF TEXAS MEDICAL BRANCH AT GALVESTON

By:

Name and Title:

Date:

THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT TYLER

By:

Name and Title:

Date:

THE UNIVERSITY OF TEXAS AT AUSTIN

By:

Name and Title:

Date:

THE UNIVERSITY OF TEXAS SOUTHWESTERN MEDICAL CENTER

By: _____

Name and Title: _____

Date: _____

THE UNIVERSITY OF TEXAS MEDICAL BRANCH AT GALVESTON

By: Angela Cook

Name and Title: Angela Cook, PhD
Director, Office Clinical Research

Date: 11-JAN-2016

THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT TYLER

By: _____

Name and Title: _____

Date: _____

THE UNIVERSITY OF TEXAS AT AUSTIN

By: _____

Name and Title: _____

Date: _____

THE UNIVERSITY OF TEXAS SOUTHWESTERN MEDICAL CENTER

By: _____

Name and Title: _____

Date: _____

THE UNIVERSITY OF TEXAS MEDICAL BRANCH AT GALVESTON

By: _____

Name and Title: _____

Date: _____

THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT TYLER

By: _____

Name and Title: David Anderson, Director, Sponsored Programs

Date: 1/12/16

THE UNIVERSITY OF TEXAS AT AUSTIN

By: _____

Name and Title: _____

Date: _____

THE UNIVERSITY OF TEXAS SOUTHWESTERN MEDICAL CENTER

By: _____

Name and Title: _____

Date: _____

THE UNIVERSITY OF TEXAS MEDICAL BRANCH AT GALVESTON

By: _____

Name and Title: _____

Date: _____

THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT TYLER

By: _____

Name and Title: _____

Date: _____

THE UNIVERSITY OF TEXAS AT AUSTIN

By: Bill Catlett

Name and Title: Bill Catlett - Director, Office of Industry Engagement

Date: 11JAN16

APPENDIX A

Appendix A – Administrative Contact Person and Address for Each Institution Named in Master Clinical Trial Agreement Between Boehringer Ingelheim Pharmaceuticals, Inc. and the Institutions of The University of Texas System

David Hawkins Associate Director, Office of Sponsored Projects **The University of Texas at Austin** P.O. Box 7726 Austin, Texas 78713-7726 Phone: 512-471-6424 Fax: 512-471-6564 Tax ID: 74-600023	Angela R. Charboneau Wishon, J.D. Vice President for Research Administration **The University of Texas Southwestern Medical Center** 5323 Harry Hines Blvd. Dallas, TX 75390-9105 Phone: 214-648-6449 Fax: 214-648-4474 Tax ID: 75-6002868
Mr. Chris G. Green, CPA Director, Office of Sponsored Programs **The University of Texas Health Science Center at San Antonio** 7703 Floyd Curl Dr, Mail Code 7828 San Antonio, TX 78229-3900 Phone: 210-567-2340 Fax: 210-567-8107 Email: contracts@uthscsa.edu Tax ID: 74-1586031	Karen Niemeier Director, Contracts **The University of Texas Health Science Center at Houston** P.O. Box 20036 Houston, TX 77225 Phone: 713-500-3999 Fax: 713-500-4939 Tax ID: 74-1761309 **Overnight address is:** 7000 Fannin Street, Suite 1006 Houston, TX 77030
David Anderson Director, Office of Pre-Award Services **The University of Texas Health Science Center at Tyler** 11937 U.S. Hwy. 271 Tyler, TX 75708-3154 Phone: 903-877-7585 Fax: 903-877-7558 Email: david.anderson@uthct.edu Tax ID: 75-6001354	Toni D'Agostino Associate VP for Research, Office of Sponsored Projects **The University of Texas Medical Branch at Galveston** 301 University Boulevard 4.40 Rebecca Sealy Hospital Galveston, TX 77555-0156 Phone: 409-266-9413 Fax: 409-266-9469 Tax ID: 74-6000949

EXHIBIT A
INDIVIDUAL CLINICAL TRIAL AGREEMENT

This Individual Clinical Trial Agreement ("ICTA") is entered into on the last date of signature below (the "Effective Date") by and between **[Institution]** ("Institution"), a member institution of The University of Texas System ("System"), with a place of business at **[Institution Address]** and **Boehringer Ingelheim Pharmaceuticals, Inc.** ("BIPI"), having its principal location at **900 Ridgebury Road/P.O. Box 368, Ridgefield, CT 06877-0368.**

RECITALS

Whereas, BIPI and Institution entered into a Master Clinical Trial Agreement ("Master Clinical Trial Agreement") effective on the _____ day of January, 2016;

Whereas, pursuant to Section 2 of the Master Clinical Trial Agreement, BIPI and Institution (collectively, the "Parties") wish to enter into this ICTA for the purpose of setting forth the name of the BIPI Investigational Product, Protocol Number, Trial Title and specific terms and conditions for the conduct of an individual Trial.

Now, therefore, pursuant to and subject to the terms and conditions of the Master Clinical Trial Agreement and in consideration of the promises and mutual covenants contained herein, the Parties agree to the following:

I. Trial Information:

BI Investigational Product:
Protocol Number:
Trial Title:

II. Investigator: Investigator is engaged in medical research on behalf of and as an employee of Institution and wishes to participate in and serve as the principal investigator on behalf of and as an employee of Institution and to conduct clinical investigations as part of the Trial as contemplated by this ICTA and the Master Clinical Trial Agreement. Investigator acknowledges that he/she has received and reviewed a copy of the Master Clinical Trial Agreement and the Protocol. Institution shall ensure that Investigator complies with the obligations, terms and conditions of the Master Clinical Trial Agreement and Protocol as if fully restated herein.

III. Additional Representations: Each party represents that this ICTA has been duly authorized, executed and delivered by such party. Each party represents that this ICTA represents the legal, valid and binding agreement of such party and is enforceable against such party in accordance with its terms. Each party represents that the person executing this ICTA on behalf of such party is authorized by such party and its governing board or management committee to do so and the execution hereof is the binding act of such party and enforceable against such party.

Each represents that the execution, delivery and performance of this ICTA by such party does not (i) require the consent, waiver, approval, license or authorization of any person or public authority which has not heretofore been obtained; (ii) violate any provision of law applicable to such party; (iii) conflict with or result in a default under any agreement or instrument; or (iv) violate any judicial or administrative decree, regulation or any other restriction of any kind or character to which such party is a party or by which such party is bound.

IV. Clinical Trial Budget and Payment Schedule: (*See* Attached Exhibit I)

V. Payee. All payments will be made by BIPI, as specified in the Form W-9 provided by Institution, payable to:

Payee: [Institution]
[Institution Address]

Tax I.D. No.: [Institution Tax ID No.]

All payments should be referenced as follows: INVESTIGATOR NAME-PROTOCOL #.

VI. Additional Notices: All communications pertaining to business matters under this ICTA shall be delivered to the person listed in Appendix A and referenced in Section 21.7 of the Master Clinical Trial Agreement and to:

Administrative Contact for Institution:

If to Investigator: **Doctor's Name**

If to Institution: **Additional Name and Address for Institution**

[Insert Section VII for Trials requiring compliance with Standard of care Flowchart:]

VII. Additional Terms and Conditions: Any additional terms added in this Section VII (a) apply only to this specific Study/Trial and (b) do not amend the terms of the Master Clinical Trial Agreement and (c) must be approved by the Institution and Office of General Counsel of The University of Texas System prior to this ICTA being executed by Institution and the Investigator. In addition to their obligations in Section 3.8 of the Master Clinical Trial Agreement, Institution and Investigator agree at all times to conduct the Trial consistent with sound scientific procedures and in accordance with the Standard of Care Flowchart attached hereto as Exhibit II.

[Institution and The University of Texas System Office of General Counsel to confirm/reconcile with ICF and IRB on Trial-by-Trial basis.]

VIII. Additional Trial Subject Injury Terms and Conditions: Any additional terms added in this Section VIII (a) apply only to this specific Study/Trial and (b) do not amend the terms of the Master Clinical Trial Agreement and (c) must be approved by the Institution and Office of General Counsel of The University of Texas System prior to this ICTA being executed by Institution and the Investigator.

In addition to the conditions of 14(a) and 14(b) in Section 14 (Trial Subject Injury) of the Master Clinical Trial Agreement, BIPI will reimburse Institution for any reasonable medical expenses incurred in providing a Trial Subject with treatment which the Institution provides to the Trial Subject pursuant to the informed consent document approved by BIPI and the IRB and signed by the Trial Subject, provided that:

(c) The Trial Subject's failure to (A) follow the directions of Investigator regarding the injury or illness, and (B) notify Investigator of the injury or illness as soon as possible following onset did not cause the injury or illness;

(d) If consistent with the terms of the ICF, Institution has exercised reasonable efforts to seek reimbursement from the Trial Subject's insurance or other third party coverage, if any (excluding governmental programs.

SIGNATURE PAGE TO FOLLOW

IN WITNESS WHEREOF, the Parties have executed this ICTA by their duly authorized officers or representatives.

BOEHRINGER INGELHEIM PHARMACEUTICALS, INC.

By: _____

Title: _____

Date: _____

[INSTITUTION]

By: _____

Title: _____

Date: _____

Read and Understood by:

INVESTIGATOR

By: _____

Date: _____

EXHIBIT I
TO INDIVIDUAL CLINICAL TRIAL AGREEMENT
CLINICAL TRIAL BUDGET
AND
PAYMENT SCHEDULE

EXHIBIT II
TO INDIVIDUAL CLINICAL TRIAL AGREEMENT
STANDARD OF CARE FLOWCHART