

*[The Accelerated Clinical Trial Agreement (ACTA) was developed to create a standard agreement to accelerate the contracting process between Sponsors and entities registered to use the ACTA. When drafting the ACTA, the entities involved brought to the discussion extensive knowledge from negotiations between Industry and university and academic medical center partners. Based on those negotiations, the language is intended to provide the optimal compromise position for both Parties. Although the ACTA is intended for multi-center clinical trials, the parties who have agreed to its terms should feel free to use it at their discretion for other types of sponsor-initiated clinical trials. This agreement has also been designed for use as a training tool for Industry Sponsors and their corresponding university/academic medical center partners. Therefore, comments have been added to clarify the specific language. The entities involved in the development of the ACTA made several concessions with regard to terms heretofore required, offering a collaborative approach. The end goal was to draft a standard agreement acceptable to both Parties in an effort to streamline and substantively reduce the delay in the contracting processes between Sponsors and academic institutions. Entities who opt to accept to the terms of the ACTA, registered at {need to add the URL}, agree to use it without changing any of the terms it contains, but for the specific Protocol (defined in Section 1.1) and Budget (defined in Section 2.1).*

*Twenty-five CTSA (Clinical and Translational Science Award) Institutions are credited with the creation of the ACTA. The UIDP (University Industry Demonstration Partnership) subsequently partnered with the CTSA institutions to nationalize and ensure the dissemination of the ACTA.]*

This Accelerated Clinical Trial (ACTA) Agreement (“Agreement”) is made as of this {DAY} day of {MONTH}, {YEAR} (the “Effective Date”) by and between {INSTITUTION NAME}, a non-profit, educational, research and healthcare institution (“Institution”) with an address at {INSTITUTION ADDRESS} and {COMPANY NAME}, a corporation having its principal place of business at {COMPANY ADDRESS} (“Sponsor”). Sponsor and Institution are herein referred to collectively as “Parties.” Individually, each of Sponsor and Institution is a “Party.”

**WHEREAS**, Institution and Sponsor have agreed to be part of the ACTA member institution group, and the Parties agree to the use this standard agreement to accelerate the process of translating laboratory discoveries into treatments for patients, to engage communities in clinical research efforts, and to train a new generation of clinical and translational researchers;

**WHEREAS**, Sponsor is a for-profit organization that intends to conduct a sponsored multicenter clinical trial, described in 1.1 below, involving the use of certain diagnostic(s), drug(s), device(s), or biologic(s) provided by Sponsor;

**WHEREAS**, the Institution has appropriate facilities and personnel with the qualification, training, knowledge, and experience necessary to conduct such a clinical trial; and

**WHEREAS**, the Study contemplated by this Agreement is of mutual interest and benefit to Institution and Sponsor, and will further the instructional and research objectives

of Institution in a manner consistent with its status as a nonprofit educational, research and health care institution;

**NOW, THEREFORE**, in consideration for the mutual promises made in this Agreement and for valid consideration, the Parties agree as follows:

## **1. Scope of Agreement**

*[Scope of Agreement explains the reason(s) the Parties are entering into an agreement and establishes the objectives the Parties wish to attain by doing so. This Section declares the intent of the Parties to conduct a sponsor-initiated, multicenter clinical trial. An important aspect from Section 1.2 below is the clarification that any conflicts between the Agreement and the Study Protocol related to business or administrative matters would be governed by the Agreement (such as publication or intellectual property), while the Protocol would govern in respect to scientific matters (e.g., adverse event reporting requirements). This Section also stipulates the provision of drug by the Sponsor, the requirement of the Parties to follow applicable laws or regulations, notice requirements related to any Protocol safety or breach issues, and the need by the Institution to obtain IRB approval prior to commencement of the Study.]*

### **Section 1.4**

*Institutions may agree to comply with laws and regulations applicable to them and their conduct of clinical trials because they have established policies, process, and training programs necessary to do so. Problems often arise during negotiations with respect to contract terms that purport to specify how a Institution must meet its legal and regulatory obligations without consideration for that Institution's existing policies, processes and training programs, e.g., the contractual specification of IT security provisions, the requirement that Institution personnel comply with specific Sponsor policy(s) (which are primarily geared at ensuing Sponsor compliance with laws, regulations, and consent decrees as applicable to the Sponsor), etc. Sponsor policies specifically drafted for Sponsor contractors often present the same issues.*

### **Section 1.6**

*This section addresses the requirements of the Association for Accreditation of Human Research Participant Protection Programs (AAHRPP). Many of the ACTA institutions are AAHRPP accredited. In order to maintain that accreditation, AAHRPP requires those institutions to include specific language in the research agreements they execute; specifically, the following elements: (i) addressing who is responsible for paying for Study subject injury; (ii) documenting Sponsor's agreement to promptly report to the Institution findings from site monitoring visits/activities that could affect Study subject safety (even if arising after Study completion) or influence the conduct of the Study; and (iii) allowing the Institution the independent right to publish its Study results. The language in this Section, as well as in Sections 9 and 12, address the required elements.]*

1.1. Institution will undertake a sponsored multicenter clinical trial ("Study") described in the protocol entitled, "{PROTOCOL TITLE}" which is attached hereto and incorporated herein as **Exhibit A** ("Protocol"). Institution will use its reasonable efforts to only recruit subjects in accordance with the Protocol. The Study will be conducted at the Institution

under the direction of {PRINCIPAL INVESTIGATOR NAME}, a {IDENTIFY ROLE; e.g., EMPLOYEE, FACULTY} of Institution (“Principal Investigator”).

1.2. In the event of any conflict between the terms and conditions of this Agreement and the Protocol or between this Agreement and any of its Exhibits, the terms and conditions of the Protocol shall control with respect to matters of the clinical conduct of the Study, and the terms of this Agreement shall control with respect to all other matters.

1.3. Unless otherwise agreed to by the Parties, Sponsor will provide to Institution on a timely basis, without charge, the required quantities of properly-labeled Sponsor drug(s) (“Study Drug”) and/or device(s) (“Study Device”) and other materials (e.g., Investigator’s Brochure, handling and storage instructions, and, if applicable, placebo) necessary for Institution to conduct the Study in accordance with the Protocol. Unless stated otherwise in writing by Sponsor, all such items are and will remain the sole property of Sponsor until administered or dispensed to Study subjects during the course of the Study. Receipt, storage, and handling of Study Drug or Study Device will be in compliance with all applicable laws and regulations, the Protocol, and Sponsor instructions.

1.4. Sponsor and Institution shall comply with and conduct all aspects of the Study in compliance with all applicable federal, state, and local laws and regulations, including generally accepted standards of good clinical practice as adopted by current FDA regulations and statutes and regulations of the U.S. Government relating to exportation of technical data, computer software, laboratory prototypes, and other commodities as applicable to academic institutions. Institution will only allow individuals who are appropriately trained and qualified to assist in the conduct of the Study.

1.5. Institution shall obtain IRB approval for this Study and proof thereof shall be provided to Sponsor. Initiation of the Protocol and Institution’s obligation to conduct the Study shall not begin until IRB approval is obtained. Institution shall obtain from each subject, prior to the subject’s participation in the Study, a signed informed consent and necessary authorization to disclose health information to Sponsor in a form approved in writing by the IRB or a waiver of consent as directed by the IRB and further provided that the informed consent is consistent with Institution’s policies.

1.6. Sponsor agrees to provide Institution with any data and safety monitoring reports related to the Study, and Institution agrees they will be submitted to the IRB as required. During the Study and for at least two (2) years following the completion of the Study at all sites, Sponsor shall promptly provide Institution and Principal Investigator with the written report of any findings, including Study results and any routine monitoring findings in site monitoring reports, and data safety monitoring committee reports including, but not limited to, data and safety analyses, and any Study information that may (i) affect the safety and welfare of current or former Study subjects, or (ii) influence the conduct of the Study. Institution and/or Principal Investigator will communicate findings to the IRB and Study subjects, as appropriate.

1.7. Institution shall promptly inform Sponsor of any urgent safety measures as instructed in the Protocol or breaches of the Protocol of which Institution becomes aware.

## **2. Payments**

*[Although the majority of contractual terms in multi-center, multi-institutional clinical trials can be standardized, the Budget and the Protocol are unique for each study contemplated. As*

*such, Exhibit B outlines a variety of payment options and considerations. Options in Exhibit B are set forth to cover both drug and device trials. Key ethical considerations for Budget negotiations with academic entities are that incentives for early completion may neither be accepted nor any product endorsement implied. The payment clause and accompanying Budget acknowledge that the Budget amounts are consistent with the mutually agreed rates for the conduct of the Study in light of the professional time and expenses required for the Study.*

*Exhibit C has been developed to facilitate both Parties in quickly identifying the correct point of contact depending upon the type of action needed, thus ensuring the smooth functioning of the trial once the ACTA has been fully executed. Exhibit C may be incorporated by reference and attached to the ACTA, but it would nonetheless be of benefit to both Parties even if not formally included in the agreement.]*

Sponsor agrees to pay Institution in accordance with the budget attached as **Exhibit B** ("Budget") on a prorated basis, according to the actual work completed and any non-cancelable obligated expenses, for subjects who are enrolled into the Study. The Parties acknowledge that the Budget amounts represent an equitable exchange for the conduct of the Study in light of the professional time and expenses required for the performance of the Study.

In addition to other necessary routing information detailed in Exhibit B, each payment shall clearly reference the: Study Protocol Number and PI name.

For administrative convenience, various Study contact information may be attached hereto and incorporated by reference as Exhibit C, entitled, "Administrative & Study Points of Contact."

The Institution's tax identification number is: \_\_-\_\_\_\_\_.

### **3. Confidentiality**

*[Recognizing that this template is intended to cover only company sponsored clinical trials, the ACTA institutions agree that the language would be more amenable to Sponsors if it protected only Confidential Information disclosed by the Sponsor to the Institution for the purposes of the Study, and did not provide mutual protection for any confidential information that might be disclosed by the Principal Investigator/Institution to the Sponsor. Although the language references the need to appropriately identify by marking the Confidential Information, it also broadly protects information that by its nature a reasonable person would consider confidential given its content and circumstance of disclosure. The requirement for verbal communications to be followed up in writing marked "confidential" was added so that Sponsors were not relying on the Institution's judgment regarding what was discussed and/or disclosed. The period of non-disclosure is identified as five years following the termination or expiration of the Agreement, which was felt to be more favorable to Sponsors than the standard three years that many Institutions require in their negotiations.]*

3.1. It is anticipated that in the performance of this Agreement, Sponsor may need to disclose to Institution information which is considered confidential. The rights and obligations of the Parties with respect to such information are as follows:

“Confidential Information” refers to information of any kind which is disclosed to the Institution by Sponsor for purposes of conducting the Study or Data (as defined below in Section 4) which:

- a) by appropriate marking, is identified as confidential and proprietary at the time of disclosure;
- b) if disclosed orally, is identified in a marked writing within thirty (30) days as being confidential; or
- c) is of such a nature that a reasonable person familiar with the Study would consider it to be confidential or proprietary from the context or circumstances of disclosure. Notwithstanding the foregoing, Data and results generated in the course of conducting the Study are not Confidential Information for publishing purposes in accordance with Section 9 of this Agreement.

Institution agrees, for a period of five (5) years following the termination or expiration of this Agreement, to use reasonable efforts, no less than the protection given their own confidential information, to use Confidential Information received from Sponsor in accordance with this Section.

Institution agrees to use Sponsor’s Confidential Information solely as allowed by this Agreement, and for the purposes of conducting the Study. Institution agrees to make Sponsor’s Confidential Information available only to those of its, or its affiliated hospitals’ employees, personnel, agents, consultants, and vendors, and approved subcontractors, as applicable, who require access to it in the performance of this Study, and are subject to similar terms of confidentiality.

3.2. The obligation of nondisclosure does not apply with respect to any of the Confidential Information that:

- a) is or becomes public knowledge through no breach of this Agreement by Institution;
- b) is disclosed to Institution by a third party entitled to disclose such information without known obligation of confidentiality;
- c) is already known or is independently developed by Institution without use of Sponsor’s Confidential Information as shown by Institution’s contemporaneous written records;
- d) is necessary to obtain IRB approval of Study or required to be included in the written information summary provided to Study subject(s) and/or informed consent form;
- e) is released with the prior written consent of the Sponsor; or
- f) is required to support the medical care of a Study Subject.

3.3. Institution may disclose Confidential Information to the extent that it is required to be produced pursuant to a requirement of applicable law, IRB, government agency, an order of a court of competent jurisdiction, or a facially valid administrative, Congressional, or other subpoena, provided that Institution, subject to the requirement, order, or subpoena, promptly notifies Sponsor. Sponsor may seek to limit the scope of such disclosure and/or seek to obtain a protective order. Institution will disclose only the minimum amount of Confidential Information necessary to comply with law or court order as advised by Institution's legal counsel.

3.4. No license or other right is created or granted hereby, except the specific right to conduct the Study as set forth by Protocol and under terms of this Agreement, nor shall any license or other right with respect to the subject matter hereof be created or granted except by the prior written agreement of the Parties duly signed by their authorized representatives.

3.5. Upon Sponsor's written request, Institution agrees to return all Confidential Information supplied to it by Sponsor at Sponsor's expense pursuant to this Agreement except that Institution may retain one (1) copy of any such Confidential Information in a secure location for purposes of identifying and satisfying its obligations and exercising its rights under this Agreement.

3.6. Institution may disclose the existence of this Agreement and any additional information necessary to ensure compliance with applicable Federal, State and Institutional policies, regulations, and laws.

#### **4. Data Use/Ownership**

*[Data is the primary "product" that results from a clinical trial. Data may take the form of notations of numeric values, measurements, symptoms, dosages, or other recorded material required by the Protocol. Data is typically recorded in a Sponsor-provided Case Report Form completed by the site for each subject enrolled, or in a report that aggregates and analyzes the Study Data. Generally, research Data is owned and controlled by the entity that records and captures the Data in readable format. In a clinical trial, universities often cede ownership to the Sponsor in explicit contract terms so that the Sponsor may compile the Data for submission to the FDA. This clause is critical to ensure clarity regarding the use of the Data.]*

*The language in this Section gives ownership rights to Sponsor for Case Report Forms, Study reports, and other Study Data generated by the Institution for the Study. Sponsor can use such Data for its own business purposes, consistent with the Study subjects' wishes as defined in the informed consent/authorization forms. The Section contains a relatively standard carve-out for source documents (e.g., subject medical records) allowing them to continue to be owned by the Institution. The Institution is also given the right to use the Data for publication purposes, per AAHRPP requirements, and other internal institutional purposes.]*

"Data" shall mean all data and information generated by Institution as a result of conducting the Study in accordance with the IRB approved Protocol. Data does not include original Study subject or patient medical records, research notebooks, source documents, or other routine internal documents kept in the Institution's ordinary course of business operations,

which shall remain the sole and exclusive property of the Institution or medical provider. Sponsor shall own and have the right to use the Data in accordance with the signed informed consent and authorization form, applicable laws, and the terms of this Agreement. Notwithstanding any licenses or other rights granted to Sponsor herein, but in accordance with the confidentiality and publication sections herein, Institution shall retain the right to use the Data and results for its publication, IRB, regulatory, legal, clinical, educational, and internal research purposes.

## **5. HIPAA/HIPAA Privacy**

*[Recognizing that Sponsors are not covered entities and, therefore, not subject to the Health Insurance Portability and Accountability Act of 1996 and its implementing regulations (HIPAA), the language in this section reflects the site's obligations under HIPAA, and focuses on compliance with privacy and related Medicare regulations. With regard to privacy, both Parties have an interest in ensuring that HIPAA regulations are not violated. Sponsors must be able to review original data, and as such, may come into contact with Protected Health Information (PHI). Institutions themselves may generate PHI, or in the case of a university affiliated with a teaching hospital, may come into contact with PHI. Consequently, all Parties are responsible for maintaining PHI in a manner consistent with HIPAA regulations. Further, since Data collected in clinical trials is generally collected under an informed consent form (ICF) and HIPAA authorization (Authorization), adhering to the applicable provisions of the ICF and Authorization helps the Parties avoid acting contrary to the requirements of HIPAA.*

*In the event the Sponsor makes a payment related to a Study-related injury, the Sponsor has obligations to report some information, which may contain PHI, to Centers for Medicare and Medicaid Services (CMS). This section also addresses the Parties' respective obligations with regard to sharing such information, and addresses limitations placed on the use of such information. Since individual Sponsors may address the handling of such payments differently, this section includes a requirement that Institutions cooperate reasonably with Sponsors in satisfying their duties under MMSEA (defined below).]*

5.1. Institution shall comply with applicable laws and regulations, as amended from time to time, including without limitation, the Health Insurance Portability and Accountability Act of 1996 and its implementing regulations (HIPAA) with respect to the collection, use, storage, and disclosure of Protected Health Information (PHI) as defined in HIPAA. Sponsor shall collect, use, store, access, and disclose PHI collected from Study subjects only as permitted by the IRB approved informed consent form or HIPAA authorization form obtained from a Study subject. Sponsor will collect, use, store, and disclose any Subject Material, defined in Section 15, it receives only in accordance with the informed consent form and, in any event, will not collect, use, store, or disclose any PHI attached to or contained within the Subject Material in any manner that would violate this Section of the Agreement.

Institution acknowledges that, pursuant to Section 111 of the Medicare, Medicaid, and SCHIP Extension Act of 2007 ("MMSEA"), Sponsor has an obligation to submit certain reports to the Centers for Medicare & Medicaid Services with respect to Medicare beneficiaries who participate in the Study and experience a research injury for which

diagnosis or treatment costs are incurred. Sponsor recognizes that Institution and Sponsor are subject to laws and regulations protecting the confidentiality of research subject information. Accordingly: (1) Institution agrees upon prior written request to provide to Sponsor, or a third-party vendor as designated by Sponsor, certain identifiable patient information required by MMSEA for Study subjects who are Medicare beneficiaries and incur medical costs in association with a research injury and whose costs are reimbursed by Sponsor pursuant to this Agreement; and (2) Institution further agrees to otherwise cooperate with Sponsor (and any third-party vendors as designated by Sponsor) to the extent necessary for Sponsor to meet its MMSEA reporting obligations.

5.2. Sponsor's ability to review the Study subjects' Study-related information contained in the Study subject's medical record shall be subject to reasonable safeguards for the protection of Study subject confidentiality and the Study subjects' informed consent form or HIPAA authorization form.

5.3. Sponsor shall not attempt to identify, or contact, any Study subject unless permitted by the informed consent form.

## **6. Record Retention**

*[21 CFR §312.62 Title 21 Food and Drugs Chapter I Food and Drug Administration Department of Health and Human Services, Subpart D: Drugs for Human Use, Part 312 Investigational New Drug Application, Subpart D—Responsibilities of Sponsor and Investigators, Section 312.62, Investigator record keeping and record retention, requires investigators to retain Study records (including drug disposition records, case histories, and supporting data) for 2 years after a marketing application is approved ("for the drug for the indication for which it is being investigated") or until 2 years after the study is discontinued and the FDA is so notified. Since Institutions participating in a Study may not know when the §312.62 retention period ends, the language in this Section provides for a fixed period; however, to make the language more acceptable to Sponsors, the timeframe may be lengthened as reasonably requested by Sponsor. After the term identified in (a) – (c), the Institution may destroy such records (and certify their destruction) only after giving prior written notice to Sponsor. If Sponsor wishes the records to remain at the Institution, the Institution agrees to continue to store them at Sponsor's reasonable storage expense. Such expenses can be addressed as a line item in the Budget if additional storage time is anticipated at the outset.]*

As applicable by law, Institution shall retain and preserve a copy of the Study records for the longer of:

- a) two (2) years after a marketing authorization for Study Drug, or Study Device has been approved for the indication for which it was investigated or Sponsor has discontinued research on the Study Drug or Study Device;
- b) such longer period as required by federal regulatory requirements; or
- c) as requested by Sponsor at Sponsor's reasonable storage expense.

## **7. Monitoring and Auditing**

*[Sponsors of clinical trials typically employ study monitors who make sure that the primary Data are collected and recorded properly. They meet periodically with research coordinators and review Study records. They ensure that the reporting of adverse events is complete. This very useful monitoring function serves to promote adherence to both the Protocol and the principles of FDA Good Clinical Practice.]*

### **Section 7.1**

*Due to the time commitment and resources needed to manage site visits, many Institutions require that the language in the Agreement identify specific timeframes as to when those site visits may occur (e.g., identifying the time interval between visits or the expectation regarding the length of the visit). To provide more amenable language for Sponsors, this Section simply requires that visits be scheduled in advance to occur at mutually agreeable times during normal business hours. Institutions will also occasionally incorporate costs for time and effort associated with not-for-cause audits.*

### **Section 7.2**

*To better address Sponsor's requests regarding potential audits, the site agrees to provide prompt notice of such an investigation and, as permissible by the regulatory agency and site policy, Sponsor may be present at the audit. The site will provide Sponsor with a copy of any formal response submitted to the regulatory agency.]*

7.1. Site visits by Sponsor and/or its authorized designee (e.g., Study monitor) will be scheduled in advance for times mutually acceptable to the Parties during normal business hours. Sponsor's and/or authorized designee's access is subject to reasonable safeguards to ensure confidentiality of medical records and systems.

7.2. Upon becoming aware of an audit or investigation by a regulatory agency with jurisdiction over the Study, Institution agrees to provide Sponsor with prompt notice of the auditor investigation. If legally permissible or allowable by the regulatory agency and permissible in accordance with the Institution's policy, Sponsor may be available or request to be present with approval from auditor during such audit, but Sponsor agrees not to alter or interfere with any documentation or practice of Institution. Institution shall be free to respond to any regulatory agency inquiries and will provide Sponsor with a copy of any formal response or documentation to the regulatory agency regarding the Study.

## **8. Inventions, Discoveries and Patents**

*[The language in this Section protects both Parties' background intellectual property. For most company-sponsored clinical trials, Sponsors require ownership of any Inventions (as defined in Section 8.2) that arise from their study. This stance deviates from the position most academic institutions take on intellectual property. An academic institution typically wants to retain ownership of any Inventions resulting from its conduct of the Study based on the Principal Investigator's knowledge and expertise, and the role that the Principal Investigator played in making an Invention in the course of the Study. In addition, because budgets are often not adequate to truly cover the academic institution's cost for conducting the Study, any royalties*

*resulting from Inventions created during the research often help to support additional research efforts by the Institution.*

*To provide a more collaborative position, the language in this Section assigns ownership of certain "Sponsor Inventions" to Sponsor. Title to "Other Inventions" (as defined in Section 8.2) would be determined by U.S. Patent Law, taking into consideration the relative contributions of the Parties to that Invention. If such Other Invention should occur, Sponsor will be granted an option to acquire an exclusive royalty-bearing license to the Institution's rights to that Other Invention. Academic institutions should consider ensuring that the Principal Investigator and research team members are aware of the impact agreeing to this Section may have on existing and future relationships with the Sponsor.]*

8.1. It is recognized and understood that certain existing inventions and technologies, and those arising outside of the research conducted under this Agreement, are the separate property of Sponsor or Institution and are not affected by this Agreement, and neither Party shall have any claims to or rights in such separate inventions and technologies.

8.2. Any new patentable inventions, developments, or discoveries made during and in the performance of the Study ("Inventions") shall be promptly disclosed to Sponsor. Title to Inventions that necessarily use or necessarily incorporate Sponsor's Study Drug and/or Study Device shall reside with Sponsor ("Sponsor Inventions"). Institution shall assign all Sponsor Inventions to Sponsor in writing. Title to Inventions other than Sponsor Inventions ("Other Inventions") shall reside with Sponsor if Sponsor personnel are the sole inventors, with Institution if Institution personnel are the sole inventors, and shall be held jointly if both Institution and Sponsor personnel are inventors.

8.3. To the extent that Institution owns sole or joint title in any such Other Inventions, Sponsor is hereby granted, without option fee other than consideration of the Study sponsored herein and the reimbursement to Institution for patent expenses incurred prior to or during the option period, an option to acquire an exclusive, worldwide, royalty-bearing license to Institution's rights to any Other Invention, which option shall extend for no more than ninety (90) days after Sponsor's receipt of an Invention disclosure from Institution ("Option Period"). The Parties shall use their reasonable efforts to negotiate, for a period not to exceed ninety (90) days after Sponsor's exercise of such option, a license agreement satisfactory to both Parties ("Negotiation Period"). In the event Sponsor fails to exercise its option within the Option Period, or the Parties fail to reach agreement on the terms of such license within the Negotiation Period, Institution shall have no further obligation to Sponsor under this Agreement with regard to the specific Other Invention.

8.4. Institution shall retain a royalty-free, irrevocable license to use for its own internal noncommercial research, educational and patient care purposes, all Sponsor Inventions or Other Inventions licensed or assigned to Sponsor hereunder.

8.5. Nothing contained in this Agreement shall be deemed to grant either directly by implication, estoppel, or otherwise any license under any patents, patent applications, or

other proprietary interest to any other inventions, discovery or improvement of either Party.

8.6. The Parties agree that the provisions of this Agreement are intended to be interpreted and implemented so as to comply with all applicable federal laws, rules, and regulations, including without limitation the requirements of Rev. Proc. 2007-47; provided, however, if it is determined by the Internal Revenue Service or any other federal agency or instrumentality (the "Government") that the provisions of this Agreement are not in such compliance, then the Parties agree to modify the provisions and the implementation of this Agreement so as to be in compliance with all applicable federal laws, rules, and regulations as determined by the Government.

## **9. Publication**

*[Non-profit, academic, and other tax-exempt Institutions must ensure that they maintain their status as mission-based entities. Universities and medical centers in particular, with their defined missions of education, research, service, and clinical care, are precluded from accepting contractual restrictions which conflict with these missions. A guiding tenet of any academic entity is to ensure academic freedom which mandates its having the ability to independently publish its results from its conduct of a Study. Failure to do so may jeopardize that Institution's tax-exempt status. In addition, AAHRPP accreditation standards require that an Institution maintain the independent right to publish the Study results. Therefore, the language drafted in this Section allows the Institution the independent right to publish. This right can be limited by a Sponsor's right of review for the presence of its Confidential Information or can be briefly delayed to permit the protection of IP rights. If the Institution is promptly notified by Sponsor during the Review Period that the publication contains Sponsor's Confidential Information, the Institution agrees to reasonably delete such Confidential Information. In addition, if Sponsor notifies the Institution that a delay in publication is needed for Sponsor to file a patent, the Institution agrees to further delay publication an additional sixty days.]*

### **Section 9.2**

*This Section pertains specifically to multicenter studies. It is understood that the first publication of the Study results will be the joint multicenter publication with the Institutions from all sites contributing Data, Study analyses, and comments. The Institution publications can be delayed up to twelve months after conclusion, abandonment, or termination of the Study at all sites.*

### **Section 9.3**

*This Section addresses requirements of the ACTA academic partners to ensure that if the Sponsor decides not to publish the multicenter Data, an academic site, upon request, could be provided access to that Data. Current regulations contain a "loophole" for investigational drugs that are not submitted for approval. This language provides for access when the Data is not otherwise maintained and/or available on a clinical trial registry or other website.]*

9.1. Institution shall be free to publish, present, or use any Data and results arising out of its performance of the Protocol (individually, a "Publication"). At least thirty (30) days prior to submission for Publication, Institution shall submit to Sponsor for review and comment

any proposed oral or written Publication ("Review Period"). Institution will consider any such comments in good faith but is under no obligation to incorporate Sponsor's suggestions. The Review Period for abstracts or poster presentations shall be thirty (30) days. If during the Review Period, Sponsor notifies Institution in writing that: (i) it desires patent applications to be filed on any inventions disclosed or contained in the disclosures, Institution will defer Publication for a period not to exceed sixty (60) days, to permit Sponsor to file any desired patent applications; and (ii) if the Publication contains Sponsor's Confidential Information as defined in Section 3 and Sponsor requests Institution in writing to delete such Sponsor's Confidential Information, the Institution agrees to delete such Sponsor's Confidential Information only to the extent such deletion does not preclude the complete and accurate presentation and interpretation of the Study results.

9.2. If this Study is part of a multi-center clinical trial, Institution agrees that the first Publication of the results of the Study shall be made in conjunction with the presentation of a joint multi-center Publication of the Study results with the Principal Investigators from all sites contributing Data, analyses, and comments. However, Institution may publish the Data and Study results individually in accordance with this Section 9 upon first occurrence of one of the following: (i) multi-center Publication is published; (ii) no multi-center publication is submitted within eighteen (18) months after conclusion, abandonment, or termination of the Study at all sites; or (iii) Sponsor confirms in writing there will be no multi-center Publication.

9.3. If no multi-center Publication occurs within eighteen (18) months of the completion of the Study at all sites, upon request by Institution, Sponsor agrees to provide such Institution access to the aggregate Data from all Study sites.

9.4. If the Institution, through its Principal Investigator, is identified to participate in the multi-center Publication: (i) Institution will have the opportunity to review the aggregate multi-center Data, upon request; and (ii) consistent with the International Committee of Medical Journal Editors (ICMJE) regulations, Institution will have adequate opportunity to review and provide input on any abstract or manuscript prior to its submission for Publication. Institution also retains the right, on behalf of its Principal Investigator, to decline to be an author on any Publication.

## **10. Use of Name**

*[Recognizing that both Parties are concerned about protecting the use of their names, trademarks, logos, etc., the language drafted for this Section has been made mutual, requiring that prior authorization is required before such disclosure can occur. However, the language does carve out disclosures by Sponsor or Institution as required by law, academic journals, professional societies, funding agencies, and applicable regulations. It also allows the Institution to publicly register information as needed for Study recruitment efforts.]*

10.1. Neither Institution nor Sponsor may use the name, trademark, logo, symbol, or other image or trade name of the other Party or its employees and agents in any advertisement, promotion, or other form of publicity or news release or that in any way implies

endorsement without the prior written consent of an authorized representative of the Party whose name is being used. Such approval will not be unreasonably withheld.

10.2. The Parties understand that the amount of any payment made hereunder may be disclosed and made public by a Party as required by law or regulation, including the Patient Protection and Affordable Care Act of 2010, provided that the disclosure clearly designates the payment as having been made to Institution for research and not to the physician.

10.3. Institution may acknowledge the Sponsor's support, including but not limited to financial support as may be required by academic journals, professional societies, funding agencies, and applicable regulations. Notwithstanding anything to the contrary in this Agreement, Sponsor agrees to allow publicly registered information about the Study to appear on Institution's clinical trials directory/website. Additionally, notwithstanding anything herein to the contrary, Institution shall have the right to post Sponsor's name, the Study title, and the Study period, and funding amount, on Institution publicly accessible lists of research conducted by the Institution.

## **11. Indemnification and Limitation of Liability**

*[Indemnification obligations are some of the most difficult contract terms to negotiate for clinical trial agreements. Both Parties wish to minimize the potential liability risk from claims by third-parties. It is not uncommon for an industry sponsor to view this as a simple matter of reallocating business risk by contract. However, from the University/non-profit's perspective it is more about compliance with law and policy and not being put in a position of acting as an insurer for a for-profit entity.]*

*There are several legal factors that potentially constrain or limit a University/non-profit's ability to be held liable on claims of alleged wrongdoing and/or their ability to indemnify against such claims. These limitations form the basis for institutional policies and negotiation approaches, and such legal constraints cannot generally be waived by contract. These can include Good Samaritan laws, volunteer protection and volunteer immunity laws, liability limitation laws, shield laws, charitable immunity laws, and specifically with respect to State entities can include State Constitutional limitations, vestiges of sovereign immunity, case law following Dillon's Rule of construction of delegated State authority, etc. As a result, broad promises of contingent liability in a contract, including indemnity provisions, run the risk of violating the law as well as being unenforceable. Particularly in the case of State Universities, in many instances they can only be held liable and/or indemnify to the extent positively and explicitly authorized by law. Nearly universal examples of such specific authorizations are the various State Tort Claims Acts, which lay out the degree and extent to which a State entity can be sued for its own negligence. Because of the preceding, and because of IRS rules and regulations relating to a non-profit's tax status, Universities have adopted policies embodying the legal scope of financial exposure that they can be responsible for with respect to industry-sponsored clinical trials.*

*The most viable approach to indemnification is one which is compliant with the law and which has a rational basis for the allocation of risk associated with each Party's performance, i.e., is*

*proportionate and is apportioned to the entity that controls the risk. Because the risks associated with the Sponsor Protocol and Drug/Device originate with and are controlled by the Sponsor, Universities are unwilling and/or legally unable to agree to take them on. However, Sponsors usually request that sites agree to indemnify for any negligence on their part, arguing that the Sponsor is contracting with the site to carry out its responsibilities in a responsible manner. This principle is generally acceptable; to the extent it is permitted or authorized by law.*

*With respect to Sponsor's responsibility to indemnify a University, many sites take the position that ordinary negligence is too broad a condition to use to potentially void such obligation as it may include an unintentional and/or relatively minor act or omission. Most appropriately, it should be material to the claim being indemnified for. Universities prefer that University gross negligence be the standard necessary to void such Sponsor's indemnification obligations, or at least establish a limit to their risk by placing a cap on their exposure. However, in order to foster an equitable agreement, this document acquiesces to ordinary negligence, without the requirement of a predetermined cap.*

### **Section 11.5**

*Universities can typically agree to language that excludes liability for special, consequential, or incidental damages as long as it doesn't exclude actual damages, and as long as the provision is bilateral.]*

11.1 Sponsor agrees to defend, indemnify, and hold harmless the Institution and its medical affiliates and affiliated hospitals, and each of their trustees, officers, directors, governing bodies, subsidiaries, affiliates, investigators, employees, IRB members, agents, successors, heirs and assigns (collectively referred to as "Institution's Indemnitees"), from and against any third party claims, loss, damage, cost and expense of claims (including reasonable attorney's fees) and suits alleged to be caused by or arising from the conduct of the Study or use of the Study Drug or Study Device under this Agreement or from the use of the Study results ("Claims"), regardless of the legal theory asserted.

11.2. Sponsor shall have no obligation to provide such indemnification to the extent that such Claim is solely caused by Institution's Indemnitee(s): (1) failure to adhere to and comply with all material and substantive specifications and directions set forth in the Protocol (except to the extent such deviation is reasonable to protect the rights, safety and welfare of the Study subjects); (2) failure to comply with all applicable laws and regulations in the performance of the Study, or (3) if such claim is directly caused by the negligent acts or omissions of Institution's Indemnites(s).

11.3. Subject to the limits and without waiving any immunities provided under applicable law (including constitutional provisions, statutes and case law) regarding the status, powers and authority of the Institution or the Institution's principal(s), Institution shall indemnify, hold harmless and defend Sponsor, its directors, officers, employees and agents, ("Sponsor's Indemnites") from and against only those third party Claims to the extent directly attributable to Institution's negligence in its conduct of the Study. Notwithstanding the above, Institution shall have no obligation to indemnify Sponsor for any other Claims (including, but not limited to, infringement or product liability Claims).

11.4. The indemnified Party shall give notice to the indemnifying Party promptly upon receipt of written notice of a Claim for which indemnification may be sought under this Agreement, provided, however, that failure to provide such notice shall not relieve indemnifying Party of its indemnification obligations except to the extent that the indemnifying Party's ability to defend such Claim is materially, adversely affected by such failure. Indemnifying Party shall not make any settlement admitting fault or incur any liability on the part of the indemnified Party without indemnified Party's prior written consent, such consent not to be unreasonably withheld or delayed. The indemnified Party shall cooperate with indemnifying Party in all reasonable respects regarding the defense of any such Claim, at indemnifying Party's expense. The indemnified Party shall be entitled to retain counsel of its choice at its own expense. In the event a Claim falls under this indemnification clause, in no event shall the indemnified Party compromise, settle or otherwise admit any liability with respect to any Claim without the prior written consent of the indemnifying Party, and such consent not to be unreasonably withheld or delayed.

11.5. EXCEPT FOR THE PARTIES' OBLIGATIONS TO INDEMNIFY EACH OTHER PURSUANT TO THIS AGREEMENT, NEITHER PARTY SHALL BE LIABLE FOR SPECIAL, CONSEQUENTIAL OR INCIDENTAL DAMAGES ARISING OUT OF OR IN CONNECTION WITH THIS AGREEMENT, EVEN IF ADVISED OF THE POSSIBILITY OF THE SAME.

## **12. Subject Injury**

*[The most important consideration in undertaking any clinical trial is that Study subjects are protected from harm or injury. Nonetheless, given the experimental nature of clinical trials, it is possible for a Study subject to experience an adverse event which may be related to participation in the Study. This Section addresses which entity is responsible for covering medical costs related to such an event.]*

*Most Institutions have policies that require Sponsors of clinical studies, in which subjects are receiving an investigational intervention or treatment, to cover the costs of any injuries or illnesses that, but for the subject's participation in the Study, would not have occurred to the subject. Regardless of whether an Institutional policy exists, the intent of requiring Sponsors to pay for such injuries is: (1) to ensure that neither the Study subject nor the Institution bears the cost of conducting the trial, the purpose of which is for FDA approval of the Sponsor's product for the particular use being studied; (2) to ensure that subjects without insurance, or with inadequate insurance, are not dissuaded from participating in the Study based upon concerns that they may be left with financial responsibilities for participating in the Study; and (3) to address Medicare and other government payer compliance laws, identifying the Sponsor as the party financially responsible for such medical costs.*

*The determination of whether an injury or illness is directly caused by the Study Drug, Study Device or Protocol procedures is intentionally the Institution's, and does not include Sponsor, nor is it limited to Principal Investigator. This is because, as the health care providers, Institutions are the parties responsible for submitting claims to private and government health insurers. Sponsors may also be biased against finding a direct causal connection between the product being tested or Protocol and the injury, and investigators may similarly be biased*

*towards finding a causal connection. Since injury or illness, that but for the subject's participation in the Study can result from both the product itself and properly performed procedures, the subject injury clause should cover injuries resulting from both the product and Protocol. However, because the Sponsor's responsibility should be limited to the injury or illness that was directly caused by participation in the Study, responsibility is limited "to the extent" it resulted from participation in the Study, as it may be the case that the injury or illness would have occurred regardless of participation, but may have been exacerbated or quickened by the Study. Similarly, it may be the case that the injury also partially resulted from the acts or omissions or the Institution. Sponsors should not be held responsible for injuries or illnesses to the extent that they were caused by the negligence or wrongful act or omission of the Institution.*

*It should be noted that sponsors often seek a carve-out from a responsibility to pay for injuries or illnesses to the extent they result from subject negligence or failure to follow the Protocol. Institutions cannot monitor subject compliance from the Protocol, and any reasonable deviation from Protocol requirements, on the part of subjects, should be expected, considered, and factored into Protocol design by Sponsors. As such, IRBs are often unwilling to accept such limitations on subject injury provisions, as obtaining the informed consent of subjects consistent with regulatory requirements and Sponsor demands would be difficult, if not impossible.*

*However, in recognition of Sponsors' needs, the ACTA offers carve-outs limiting Sponsor's obligations to pay to the extent the expenses for Subject Injury are not caused by the Institution's negligence (e.g., if a Study subject is injured because of faulty instructions by the Institution) or caused by the natural progression of an underlying or pre-existing condition.*

*Medicare secondary payer (MSP) regulations require that the Sponsors agree to pay for medically necessary services related to injuries Study subjects may receive as a result of participation in the trial. Academic Institutions are precluded from seeking reimbursement from Medicare or commercial payers. This stance is based on the Centers for Medicare and Medicaid Services' (CMS) stated position that a Sponsor's agreement to pay for research related injuries is de facto a demonstration of the Sponsor's responsibility to pay. In May 2010, CMS sent out an alert directed at Sponsors of clinical trials who make payments for complications or injuries related to trials that such payments are considered to be payments by liability insurance (including self-insurance) and must be reported under the MSP mandatory reporting provisions in Section 111 of the MMSEA.]*

If a Study subject suffers an adverse reaction, illness, or injury which, in the reasonable judgment of Institution, was directly caused by a Study Drug or Study Device or any properly performed procedures required by the Protocol, Sponsor shall reimburse for the reasonable and necessary costs of diagnosis and treatment of any Study subject injury, including hospitalization, but only to the extent such expenses are not attributable to (i) Institution's negligence or willful misconduct or (ii) the natural progression of an underlying or pre-existing condition or events, unless exacerbated by participating in the Study.

## **13. Insurance**

*[Both Sponsors and Institutions have limitations with regard to the level of insurance coverage they maintain to cover their obligations under clinical trial agreements. Instead of placing specific dollar amounts of Institutions and Sponsors in the ACTA, in order to make the language more acceptable to each Party, this Section identifies limits for the Parties. The Institution's insurance limits are generally in the range of \$1,000,000 (\$1M) and \$3,000,000 (\$3M) aggregate. Because some of the Institutions can agree to higher limits, the language drafted for this Section states "at least" \$1M and \$3M, allowing some of the private/State Institutions who could not agree to more than the \$1M and \$3M aggregate to participate, but documenting the potential for additional coverage for other Institutions who could agree to higher limits. Sponsor's insurance limits are generally in the range of \$3M and \$10M aggregate.]*

### **Section 13.3**

*[The requirements regarding providing evidence of insurance coverage and notification if there is a material change in its coverage which would affect either party's ability to meet its obligations under this Agreement.]*

13.1. Institution shall, at its sole cost and expense maintain a policy or program of insurance or self-insurance at the level of at least \$1,000,000 per occurrence (or per claim) and \$3,000,000 annual aggregate to support its obligations assumed in this Agreement. However, if Institution is a public entity entitled to governmental immunity protections under applicable state law, then Institution may provide liability coverage in accordance with any limitations associated with the applicable law.

13.2. Sponsor shall, at its sole cost and expense, procure and maintain commercial general liability insurance, clinical trial insurance and products liability insurance or equivalent self-insurance, unless otherwise indicated in an attached work order, in amounts not less than \$3,000,000 per occurrence and \$10,000,000 annual aggregate. Such commercial general liability insurance, clinical trial insurance and products liability insurance or equivalent self-insurance shall provide contractual liability coverage for Sponsor's indemnification obligations herein.

13.3. Upon written request, either Party will provide evidence of its insurance or self-insurance acceptable to the other Party. Either Party will provide the other Party with written notice of material change in its coverage which would affect such Party's ability to meet its obligations under this Agreement. A Party's inability to meet its insurance obligation constitutes material breach of this Agreement.

## **14. Term and Termination**

*[Due to the high cost of initiating a site, many Sponsors are unwilling to accept the inclusion of broad termination language providing Institutions with the right to terminate with or without cause, although Institutions typically require such broad termination rights. To make the language more collaborative, an Institution's right to terminate for convenience has not been*

*included in the ACTA, however, an Institution may be terminated for the following limited causes: (i) for subject safety reasons; (ii) in the event the Principal Investigator becomes unavailable and the Parties cannot find an acceptable successor; and (iii) when the Sponsor is in material default/breach. If the Study is terminated early, the Institution will cooperate with Sponsor to provide an orderly wind-down of the Study.]*

14.1. This term of this Agreement shall commence upon the Effective Date and terminate upon the completion of the Parties' Study-related activities under the Agreement, unless terminated early as further described in this Section.

14.2. Sponsor has the right to terminate the Study upon thirty (30) days prior written notice to the Institution. This Study may be terminated immediately at any time for any reason by the Institution or Sponsor when, in their judgment or that of the Principal Investigator, the Institution's IRB, Scientific Review Committee, if applicable, or the Food and Drug Administration, it is determined to be inappropriate, impractical, or inadvisable to continue, in order to protect the Study subjects' rights, welfare, and safety, or the IRB otherwise disapproves the Study. If for any reason Principal Investigator becomes unavailable to direct the performance of the work under this Agreement, Institution shall notify Sponsor. If the Parties are unable to identify a mutually acceptable successor, this Agreement may be terminated by either Party upon thirty (30) days written notice.

14.3. Notwithstanding the above, any Party may, in addition to any other available remedies:

- a) immediately terminate this Agreement upon the other Party's material failure to adhere to the Protocol, except for deviation required to protect the rights, safety, and welfare of Study subjects; and/or
- b) terminate this Agreement upon the other Party's material default or breach of this Agreement, provided that the defaulting/breaching Party fails to remedy such material default, breach, or failure to adhere to the Protocol within thirty (30) business days after written notice thereof.

14.4. In the event that this Agreement is terminated prior to completion of the Study, for any reason, Institution shall:

- a) notify the IRB that the Study has been terminated;
- b) cease enrolling subjects in the Study;
- c) cease treating Study subjects under the Protocol as directed by Sponsor to the extent medically permissible and appropriate;
- d) terminate, as soon as practicable, all other Study activities; and
- e) furnish to Sponsor any required final report for the Study in the form reasonably acceptable to Sponsor.

Promptly following any such termination, Institution will provide to Sponsor copies of Data collected pursuant to the Study Protocol. Upon Sponsor's written request, Institution shall

provide to Sponsor all Sponsor's Confidential Information provided under this Agreement provided, however, that Institution may retain one (1) copy of Confidential Information for record keeping purposes, monitoring its obligations, and exercising its rights hereunder, subject to Institution's ongoing compliance with the confidentiality and non-use obligations set forth in this Agreement.

14.5. If this Study is terminated early by either Party, the Institution shall be reimbursed for all work completed, on a pro rata basis, and reasonable costs of bringing the Study to termination incurred through the date of termination, and for non-cancelable commitments properly incurred through that date. Upon receipt of notice of termination, Institution will use reasonable efforts to reduce or eliminate further costs and expenses and will cooperate with Sponsor to provide for an orderly wind-down of the Study.

14.6. Subsections 1.4, 1.6, and 14.6, and Sections 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 15, 19 and 23, shall survive any termination or expiration of this Agreement, except that Section 3 shall survive for the period stated in Section 3.1. Any provision of this Agreement that by its nature and intent remains valid after termination will survive termination.

## **15. Subject Material**

*[For some studies, the Institution may be asked to provide bio-specimens to Sponsor to be used in accordance with the Protocol for the purposes of that Study. Often Institutions require language in the contract documenting the Institution's ownership of such bio-specimens and adding any requirements based on the Institution's policies (e.g., returning or destroying the samples upon completion or expiration of the Study). The Institutions agreed that to make this Section more amenable to Sponsors, such requirements have not been included. Sponsor's use of Subject Material must be consistent with the law and Study subject's wishes as documented in the informed consent form. If the Sponsor wishes to use the bio-specimens for future research, Section 15.2 addresses the need for additional Institutional Review Board review and approval.]*

15.1. Subject Material means any biologic material of human origin including, without limitation, tissues, blood, plasma, urine, spinal fluid, or other fluids derived from the Study subjects in accordance with and pursuant to the Protocol ("Subject Material").

15.2. Institution agrees to make the Subject Material available to the Sponsor in accordance with the Protocol for the purposes of the Study. The Subject Material may be used by the Sponsor, central lab, or other contracted party only as allowed by the Study subject's informed consent form or pertinent institutional review board(s). Sponsor agrees that any use of Subject Materials, other than as allowed by the Study subject's informed consent form, will require additional IRB review and approval.

## **16. Subcontract**

*[Some of the Institutions have affiliated member site(s): these may include academic medical centers and hospitals. The purpose of this provision is to allow for a Study to be subcontracted with those sites with written approval of Sponsor. As is the case when any Subcontract is contemplated, the terms and conditions of the prime award flow down to the Subcontractor so*

*that all obligations for Study completion are in alignment. This Section is particularly relevant in situations where State laws regarding contractual terms are limited. In such cases, the State entity may have established a 501(c)3 non-profit corporation to whom clinical trials are issued. In turn, that 501(c)3 will subcontract with the university and/or academic medical center to accomplish the work.]*

Institution has the right to subcontract to other sites to conduct the Study in accordance with the Protocol with terms consistent with this Agreement with written approval of the Sponsor, which approval shall not be unreasonably withheld. If Institution subcontracts any Study related duties, Institution shall contract with such subcontractors incorporating terms substantially similar to the terms herein. Such subcontracts may be provided to the Sponsor upon written request. The Sponsor has the right to subcontract to a third-party CRO or Academic Research Organization (ARO) and assign Study-related duties and rights to any Sponsor affiliate. If Sponsor subcontracts any Study-related duties and rights, Sponsor remains responsible for any of those duties and rights.

## **17. Notices**

*[The purpose of this Section is to insure all necessary Parties provide a valid address, so that any appropriate notices are correctly sent. It is important to agree to what constitutes valid notice. For example, "upon confirmation of delivery by receipt" is preferable to "5 days after mailed" as the former is verifiable.]*

Any notice, authorization, approval, consent or other communication will be in writing and deemed given:

- a. Upon delivery in person;
- b. Upon delivery by courier;
- c. Upon delivery date by a nationally-recognized overnight delivery service such as FedEx.

### **If to Sponsor:**

{SPONSOR NAME}  
{CONTACT NAME}  
{CONTACT TITLE}  
{ADDRESS LINE}  
{TELEPHONE NUMBER}  
{FAX NUMBER}  
{E-MAIL ADDRESS}

### **If to Institution:**

{INSTITUTION NAME}  
{CONTACT NAME}  
{CONTACT TITLE}  
{ADDRESS LINE}  
{TELEPHONE NUMBER}  
{FAX NUMBER}  
{E-MAIL ADDRESS}

### **With a copy to Principal Investigator:**

{PRINCIPAL INVESTIGATOR NAME}

{PRINCIPAL INVESTIGATOR TITLE}  
{ADDRESS LINE}  
{TELEPHONE NUMBER}  
{FAX NUMBER }  
{E-MAIL ADDRESS}

## **18. Independent Contractor**

*[This Section makes it clear that neither Party is legally bound to the other apart from the existence and terms of the specific Agreement. Neither Party is financially responsible for the acts or omissions of the other Party's employees or agents, nor responsible for any tax obligations to such other Party's employees or agents, other than as required pursuant to Section 11 (Indemnification and Limitation of Liability) and Section 12 (Subject Injury) of the ACTA. Further, neither Party owes the other duties of loyalty upon the other as a fiduciary or agent.]*

It is mutually understood and agreed that the relationship between Parties is that of independent contractors. Neither Party is the agent, employee, partner, joint venturer, or servant of the other. Except as specifically set forth herein, neither Party shall have nor exercise any control or direction over the methods by which the other Party performs work or obligations under this Agreement. Further, nothing in this Agreement is intended to create any partnership, joint ventures, lease, or equity relationship, expressly or by implication, between the Parties.

## **19. Clinical Trial Registry**

*[The requirements set out under U.S. Federal law enacted in 2007, Section 801 of the Food and Drug Administration Amendments Act (FDAAA 801), instruct the "responsible party" of "applicable clinical trials" to register the study and submit trial results to the Clinical Trial Registry Data Bank. The person who initiates the clinical trial is responsible for registering the trial and submitting the trial information to the Clinical Trial Registry Data Bank. An applicable drug trial is one that meets four criteria: (i) controlled; (ii) clinical investigation; (iii) other than a Phase I trial; and (iv) drug, subject to Section 505 of the Federal Food, Drug, and Cosmetic Act (a drug) or Section 351 of the Public Health Service Act (a biological product). The responsible party must register a study no later than 21 days after enrollment of the first subject. The International Committee of Medical Journal Editors (ICMJE) encourages registration of research with non-trial designs, but because the exposure or intervention in non-trial research is not dictated by the researchers, the ICMJE does not require it.]*

Prior to enrollment of the first subject in the Study, Sponsor agrees to ensure that the Study is fully registered on [www.clinicaltrials.gov](http://www.clinicaltrials.gov) in accordance with the requirements of the International Committee of Medical Journal Editors (ICMJE) and Public Law 110-85. Results of this Study will be reported in compliance with applicable laws.

## **20. Non-Referral/Anti-Corruption Language**

*[Section 20.1*

*This Section documents the intent of the Parties to define a relationship that represents a fair market value exchange, and is not intended to encourage the unlawful referral of subjects or business between the Parties.*

#### *Section 20.2*

*Some of the CTSA Institutions have been asked during negotiations with Sponsors to include anti-corruption language. To meet that request, Section 20.2 incorporates such anti-corruption language.]*

20.1. The Parties agree that it is not their intent under this Agreement to induce or encourage the unlawful referral of subjects or business between the Parties, and there shall not be any requirement under this Agreement that either Party, its employees or affiliates, including its medical staff, engage in any unlawful referral of subjects to, or order or purchase products or services from, the other Party.

20.2. Each Party shall require that their employees, who are involved in the conduct of the Study, will not offer, pay, request or accept any bribe, inducement, kickback or facilitation payment, and shall not make or cause another to make any offer or payment to any individual or entity for the purpose of influencing a decision for the benefit of the other Party.

## **21. Force Majeure**

*[The purpose of this Section, which is generally present in contracts, is to cover situations which may arise during the term of the ACTA that cause work to be stopped for a period of time, or altogether, and are outside the reasonable control of the Parties. Force majeure is not intended to relieve the Parties of negligent acts, or malfeasance, but rather addresses the possibility that circumstantial events may prevent a Party from meeting its contractual obligations to the other Party. If such circumstances should arise, the Parties are obliged to provide timely notification of the event that has caused an interruption. In any such (rare) circumstances, the Parties will work together to create a plan that will allow work to resume when the circumstances necessitating the delay have been remedied. In circumstances where the situation cannot be remedied in a suitable timeframe, the Parties agree to a termination of the ACTA without seeking legal remedy.]*

If either Party hereto shall be delayed or hindered in, or prevented from, the performance of any act required hereunder for any reason beyond such Party's direct control, including but not limited to, strike, lockouts, labor troubles, governmental or judicial actions or orders, riots, insurrections, war, acts of God, inclement weather, or other reason beyond the Party's control (a "Disability") then such Party's performance shall be excused for the period of the Disability. Any Study timelines affected by a Disability shall be extended for a period equal to the delay and any affected Budget shall be adjusted to account for cost increases or decreases resulting from the Disability. The Party affected by the Disability shall notify the other Party of such Disability as provided for herein.

## **22. Counterparts**

This Agreement may be executed in any number of counterparts, each of which shall be an original and all of which together shall constitute one and the same document, and is binding on all Parties notwithstanding that each of the Parties may have signed different counterparts. Facsimiles or scanned copies of signatures or electronic images of signatures shall be considered original signature unless prohibited by applicable law.

## **23. Debarment**

*[The purpose of this Section is to ensure that the Institution agrees to comply with the Code of Federal Regulations Title 21 Food and Drugs Chapter I–Food and Drug Administration Debarment of Health and Human Services Subchapter D-Drugs for Human Use, Part 312–Investigational New Drug, Subpart D–Responsibilities of Sponsors and Investigators, Section 312.70 Disqualifications of a Clinical Investigator, which outlines the process to be undertaken to initiate the investigation of reported or identified situations of repeated and deliberate non-compliance or submission of false information to the FDA.]*

*This language provides a fair opportunity to a University to be on notice in order to meet its obligation to provide the necessary notice to a Sponsor under this ACTA.]*

The Institution certifies that to its knowledge neither it, nor any of its employees, agents or other persons performing the Study under its direction, is currently debarred, suspended, or excluded under the Federal Food, Drug and Cosmetic Act, as amended, or disqualified under the provisions of 21 CFR §312.70. In the event that the Principal Investigator or any Study personnel becomes debarred or disqualified during the term of this Agreement or within 1 year after termination of the Study, the Institution agrees to promptly notify Sponsor after learning of such event. Institution certifies that it is not excluded from a federal health care program, including Medicare and Medicaid. In the event an Institution becomes excluded during the term of this Agreement or within 1 year after termination of the Study, the Institution agrees to promptly notify Sponsor after learning of such event.

## **24. Choice of Law –Intentionally omitted**

*[While ‘choice of law’ or ‘governing law’ provisions often appear in contracts, this ACTA does not contractually specify what law will govern the interpretation and enforcement of this ACTA. Parties often wish to specify the application of a particular State’s law through contract, based on a rationale of relatedness or based on the nature of their connection to that State (e.g., the state where the University or Sponsor is incorporated, conducts business, or is located). The benefits of specifying the application of a particular State’s law include certainty and a potentially positive legal bias. Though it is not often the preferred position taken in any organization’s template agreement, remaining silent is nearly universally acceptable to both industry and Universities in clinical trial agreements, and is maintained as the consensus position here.]*

## **25. Entire Agreement**

Section and clause headings are used herein solely for convenience of reference and are not intended as substantive parts of the Parties’ agreement. This ACTA incorporates the

Exhibits referenced herein. This written ACTA constitutes the entire agreement between the Parties concerning the subject matter, and supersedes all other or prior agreements or understandings, whether written or oral, with respect to that subject matter. Any changes made to the terms, conditions or amounts cited in this ACTA require the written approval of each Party's authorized representative.

The authorized representatives of the Parties have signed this ACTA as set forth below.

{INSTITUTION}

{SPONSOR}

By: \_\_\_\_\_  
{NAME}

By: \_\_\_\_\_  
{NAME}

Title: \_\_\_\_\_

Title: \_\_\_\_\_

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

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

**READ AND ACKNOWLEDGED**

By: \_\_\_\_\_  
{PRINCIPAL INVESTIGATOR}

Title: \_\_\_\_\_

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

*[PI Signature Block: The PI is usually an employee of the Institution and, therefore, not empowered to act as a legal signatory. However, it is in the best interest of both Parties that the PI, as the key implementer of the Study, signal his/her awareness of the terms entailed. There are also various State conflict of interest laws that may, among other things, prohibit an employee from being a Party to an Agreement in which his/her employer is a Party. As such, the simplest solution is to leave the PI signature block as a straightforward acknowledgement that he/she is familiar with the contractual obligations contained in the Agreement and prepared to assume responsibility for the work to be undertaken.]*

**READ AND ACKNOWLEDGED**

By: \_\_\_\_\_  
{PRINCIPAL INVESTIGATOR}

Title: \_\_\_\_\_

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

## **Exhibit B**

## **Exhibit C**