

# Investigator-Initiated Accelerated Clinical Trial Agreement

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

**WHEREAS**, the Institution and Company have agreed to use the 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**, Institution has approached Company to provide support, financial and/or otherwise, to Institution for the conduct of a clinical trial under the Protocol referenced below (“Study”); and

**WHEREAS**, Company desires to provide such support to enable Institution to conduct the Study, and 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 Company, 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**

1.1. Institution will conduct the Study described in the protocol entitled, “{PROTOCOL TITLE and Protocol designation}” which is attached hereto and incorporated herein as **Exhibit A** (“Protocol”), under the direction of {SPONSOR 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. **(OMIT IF DRUG, DEVICE, OR EQUIPMENT ARE NOT BEING SUPPLIED BY COMPANY.)** For Company provided Equipment, see **Exhibit B** (“Equipment”).

Unless otherwise agreed to by the Parties, Company will provide to Institution on a timely basis, without charge, the required quantities of properly-labeled Company drug(s) or biologic(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 or comparator drug) necessary for Institution to conduct the Study in accordance with the Protocol. Unless stated otherwise in writing by Company, all such items

are and will remain the sole property of Company until administered or dispensed to Study subjects during the course of the Study. Receipt, storage, and handling of Study Drug/Device will be in compliance with all applicable laws and regulations, the Protocol, and written Company instructions. *For the avoidance of doubt, when a Study Drug and comparator drug are supplied by Company and are used in combination in accordance with the Protocol, both are deemed to be Study Drug.*

1.4. Company 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. 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 Company 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. Parties agree to promptly, or in a timely manner appropriate to the risk involved, notify each other in writing upon receipt of any information that could affect the safety and/or medical care of current or former subjects, and/or affect the willingness of subjects to continue their participation in the clinical trial, and/or influence the conduct of the Study, and/or alter the IRB's approval. Institution and/or Principal Investigator will communicate findings to the IRB and Study subjects, as appropriate.

## 2. Payments

### (ONLY AS APPLICABLE)

Company agrees to pay Institution in accordance with the budget attached as **Exhibit C** ("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 C, 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 D**, entitled, "Administrative & Study Points of Contact."

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

### 3. Confidentiality

3.1. "Confidential Information" refers to information of any kind related to the Study which is disclosed by one party ("Discloser") to the other party ("Recipient") for purposes of conducting the Study which:

- a) by appropriate marking, is identified as confidential and proprietary at the time of disclosure; or
- b) if disclosed orally, is identified in a marked writing within thirty (30) days as being confidential.

Each Party will make reasonable efforts to mark Confidential Information as stated in (a) and (b) above. However, to the extent such marking is not practicable, then in the absence of written markings, information disclosed (written or verbal) that a reasonable person familiar with the Study would consider to be confidential or proprietary from the context or circumstances of disclosure shall be deemed as such.

Subject to Section 9, neither party will disclose Confidential Information of the other without the other party's authorization. This provision shall remain in effect for five (5) years following the termination or expiration of this Agreement.

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 Recipient;
- b) is disclosed to Recipient by a third party entitled to disclose such information without known obligation of confidentiality;
- c) is already known or is independently developed by Recipient without use of Discloser's Confidential Information as shown by Recipient'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 Discloser;
- or
- f) is required to support the medical care of a Study subject.

3.3. Either Party 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 subject to the requirement, order, or subpoena the other Party is notified if legally permissible. To the extent allowed under applicable law, Discloser may seek to limit the scope of such disclosure and/or seek to obtain a protective order. Recipient will disclose only the minimum amount of Confidential Information necessary to comply with law or court order as advised by Recipient'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 Discloser's written request, Recipient agrees to return all Confidential Information supplied to it by Discloser at Discloser's expense pursuant to this Agreement except that Recipient may retain such Confidential Information in a secure location for purposes of identifying and satisfying its obligations and exercising its rights under this Agreement.

3.6 Either party 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**

Institution shall be the sole and exclusive owner of all Study subjects' medical records, the Protocol, and Study data and results. The Institution will provide the Deliverables as defined in Exhibit E, in confidence to Company. Company has the right to use such Deliverables in its research and development of the Study Drug/Device, provided that such use does not prevent Institution from publishing in accordance with Section 9.

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

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. In the event that Company is provided with individually identifiable health information, including, but not limited to, PHI (as that term is defined by HIPAA), Company will maintain the confidentiality of all such information, unless specifically required to disclose such information by law, and will use it only as allowed by the Study subject's informed consent form.

5.2. Company shall not attempt to identify, or contact, any Study subject unless permitted by the Study subject's informed consent form.

#### **6. Record Retention**

Institution shall maintain and retain Study records as applicable by law.

#### **7. Auditing**

Upon becoming aware of an audit or investigation by a regulatory agency with jurisdiction over the Study, Institution agrees to provide Company 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, Company may be available or request to be present with approval from auditor during such audit, but Company 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 Company with a copy of any formal response or documentation to the regulatory agency regarding the Study.

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

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 Company or Institution and are not affected by this Agreement, and neither Company nor Institution shall have any claims to or rights in such separate inventions and technologies.

8.2. Title to any new inventions, developments, or discoveries arising during and in the course of the performance of the Study under this Agreement ("Inventions") that are made solely by Institution personnel ("Institution Inventions") shall be in Institution, in accordance with U.S. Patent Law, Title 35 United States Code, and shall be promptly disclosed in writing to Company. Inventorship shall be determined in accordance with U.S. Patent Law or by mutual agreement if the invention is not patentable.

Title to any Inventions made solely by Company personnel ("Company Inventions") shall be in Company, in accordance with U.S. Patent Law, Title 35 United States Code or by mutual agreement if the invention is not patentable.

Each Invention conceived, made or reduced to practice jointly by employees of both Institution and Company shall be jointly owned ("Joint Invention"). Inventorship shall be determined in accordance with U.S. Patent Law or by mutual agreement if the invention is not patentable. Institution's obligations under Section 8 shall be performed by institution's appropriate office with technology transfer responsibilities, if required by and in accordance with its respective policies.

8.3. Company shall have an option to negotiate an exclusive, subject to any third party rights, worldwide, royalty-bearing license to Institution's rights to any Institution or Joint Invention, which option shall extend for ninety (90) days after Company's receipt of an invention disclosure. Upon Company's exercise of the option, the parties shall promptly negotiate a license agreement in good faith. If, after one hundred twenty (120) days from Company's receipt of an invention disclosure, Company and Institution are unable to execute a license pursuant to the option, then Institution is free to license its rights to said Institution or Joint Invention to a third party, and Institution shall have no further obligations to Company under such Institution or Joint Invention.

8.4. 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.

8.5. 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**

Institution shall be free to publish and/or present about the Study, including but not limited to use of 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 Company 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 Company's suggestions. The Review Period for abstracts or poster presentations shall be thirty (30) days. If during the Review Period, Company 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 Company to file any desired patent applications; and (ii) if the Publication contains Company's Confidential Information as defined in Section 3 and Company requests Institution in writing to delete such Company's Confidential Information, the Institution agrees to delete such Company's Confidential Information only to the extent such deletion does not preclude the complete and accurate presentation and interpretation of the Study results.

## **10. Use of Name**

10.1. Neither Institution nor Company 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 other Party whose name is being used. Such approval will not be unreasonably withheld.

10.2. Institution and Company understand that the amount of any payment made hereunder may be disclosed and made public by the other 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 Principal-Investigator.

10.3. Institution may acknowledge the Company'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, Institution may publically post 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 Company'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**

11.1 Company 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 attorneys' fees) and suits ("Claims"), alleged to be caused by or arising from the Company's (1) negligent acts or omissions in fulfilling its obligations pursuant to this Agreement; (2) use of the Deliverables or Inventions; (3) failure to comply with all applicable laws and regulations in the performance of the Agreement; or (4) defects in manufacturing or labeling of the Study Drug/Device.

11.2. Company 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 comply with all applicable laws and regulations in the performance of the Study, or (2) if such claim is directly caused by the negligent acts or omissions of Institution's Indemnitees(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 Company, its directors, officers, employees and agents, ("Company's Indemnitees") from and against only those third party Claims to the extent directly attributable to Institution's negligent acts or omissions in the conduct of the Study . Notwithstanding the above, Institution shall have no obligation to indemnify Company 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 AS STATED ABOVE, NEITHER PARTY SHALL BE LIABLE TO THE OTHER PARTY 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 (required only if Company is providing product)**

If a Study subject suffers an adverse reaction, illness, or injury which, in the reasonable judgment of Investigator, was directly caused by a defect in the manufacture or shipment of the Company's Study Drug/Device, Company 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 Institution's negligence or willful misconduct.

## **13. Insurance**

13.1.

Institution shall, at its sole cost and expense maintain a policy or program of insurance or self- insurance

sufficient to support its obligations under 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. Company 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, in amounts not less than \$3,000,000 per occurrence and \$5,000,000 annual aggregate, unless otherwise indicated in an attachment. Such commercial general liability insurance, clinical trial insurance and products liability insurance or equivalent self-insurance shall provide contractual liability coverage for Company'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. A Party's inability to meet its insurance obligation constitutes material breach of this Agreement.

## **14. Term and Termination**

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. Either party has the right to terminate the Study upon thirty (30) days prior written notice to the other. This Study may be terminated immediately at any time for any reason by either party 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 Company. 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) 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 Company support has been terminated and;
- b) furnish to Company any Deliverables for the Study completed prior to Termination.

- c) Upon Discloser's written request, Recipient shall provide Discloser at Discloser's expense, all Confidential Information provided under this Agreement by Discloser; provided, however, that Recipient may retain such Confidential Information for record keeping purposes, monitoring its obligations, and exercising its rights hereunder, subject to Recipient'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, if applicable. Upon receipt of notice of termination, Institution will use reasonable efforts to reduce or eliminate further costs and expenses.

14.6. **(REVISE IF SECTIONS ARE OMITTED DUE TO STRUCTURE)** Subsections 1.4, 1.6, 14.4, 14.5 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 (OMIT IF MATERIALS ARE NOT BEING PROVIDED TO THE COMPANY)**

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 Company in accordance with the Protocol for the purposes of the Study. The Subject Material may be used by the Company, central lab, or other contracted party only as allowed by the Study subject's informed consent form or pertinent institutional review board(s). Company 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**

If applicable, Institution has the right to subcontract to other sites ("Sites") to conduct the Study in accordance with the Protocol with terms consistent with this Agreement with written approval of the Company, which approval shall not be unreasonably withheld. Institution shall contract with such Sites incorporating terms substantially similar to the terms herein. Company acknowledges and affirms that any rights, benefits and protections it affords to Institution will be afforded to Sites.

## **17. Notices**

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 Company:**  
{COMPANY NAME}

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

**If to Institution:**

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

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

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

**18. Independent Contractor**

It is mutually understood and agreed that the relationship between Institution and Company is that of independent contractors. No Party shall represent itself as 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**

If applicable, prior to enrollment of the first subject in the Study, Institution 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**

20.1. The Institution and Company 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. Institution and Company agree 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**

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. Scanned copies of signatures or electronic images of signatures shall be considered original signature unless prohibited by applicable law.

## **23. Debarment**

Parties each represent and certify that they are not, and their Study personnel are not, debarred under the provisions of the Generic Drug Enforcement Act of 1992, 21 U.S.C. §335(a) and (b) or sanctioned by a Federal Health Care Program (as defined in 42 U.S.C. Sec. 1320 a-7b(f)), including, but not limited to the federal Medicare or a state Medicaid program, or debarred, suspended, excluded or otherwise declared ineligible from any Federal agency or program in connection with the conduct of the Study hereunder. In the event that during the term of this Study, Company, Investigator, or Study personnel becomes debarred, suspended, excluded, sanctioned, or otherwise declared ineligible from such Federal Programs for which they were previously participating in, the party shall immediately notify the other party. Both parties also agree that, if their respective Study personnel become debarred, suspended, excluded, sanctioned, or otherwise declared ineligible, either party has the right to immediately terminate this Agreement in accordance with Article 14, without any further action or notice by either party.

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

## **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 Agreement incorporates the Exhibits referenced herein. This written Agreement 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 Agreement require the written approval of each Party's authorized representative.

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

{INSTITUTION}

{COMPANY}

By: \_\_\_\_\_

By: \_\_\_\_\_

{NAME}

{NAME}

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

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

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

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

**READ AND ACKNOWLEDGED**

By: \_\_\_\_\_

{INVESTIGATOR}

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

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

**EXHIBIT A**  
Protocol

**EXHIBIT B**  
Equipment

**The following shall be defined as Equipment as described in Section 1 of the Investigator-Initiated Accelerated Clinical Trial Agreement (II-ACTA).**

**Equipment:** (include a list of Equipment and any terms associated with the Equipment)

**EXHIBIT C**

Budget

**EXHIBIT D**

Administrative & Study Points of Contact

**EXHIBIT E**  
Deliverables

The following shall be defined as Deliverables as described in Section 4 of the Investigator-Initiated Accelerated Clinical Trial Agreement (II-ACTA).

**Deliverables**

*Add due dates or reporting frequency as applicable.*

<b>Deliverable(s) and Description (may include interim or final reports, data, or specimens)</b>