CTNeT
STATEWIDE CLINICAL TRIALS NETWORK OF TEXAS

Network Clinical Trial Agreement

By and between

Statewide Clinical Trials Network of Texas (CTNeT)

And

member institutions of

The University of Texas System:

The University of Texas Health Science Center at San Antonio

The University of Texas Health Science Center at Houston

The University of Texas Health Science Center at Tyler

The University of Texas M. D. Anderson Cancer Center

The University of Texas Medical Branch at Galveston

The University of Texas Southwestern Medical Center

The University of Texas at Austin

The University of Texas at El Paso

August 15, 2012

STATEWIDE CLINICAL TRIALS NETWORK OF TEXAS

NETWORK CLINICAL TRIAL AGREEMENT

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NETWORK CLINICAL TRIAL AGREEMENT

This Network Clinical Trial Agreement (this "**Agreement**") is made and entered into effective as of the 1st day of August, 2012 (the "**Effective Date**") by and between the Statewide Clinical Trials Network of Texas ("**CTNeT**"), a Texas non-profit corporation whose principal place of business is 5080 Spectrum Drive, Suite 600W, Dallas, Texas 75001, and the following member institutions of The University of Texas System: The University of Texas Health Science Center at San Antonio, The University of Texas Health Science Center at Houston, The University of Texas Health Science Center at Tyler, The University of Texas M. D. Anderson Cancer Center, The University of Texas Medical Branch at Galveston, The University of Texas Southwestern Medical Center, The University of Texas at Austin, and The University of Texas at El Paso ("each a **Research Site"**), each with an office and place of business as set forth on Exhibit D (collectively, the "**Parties**" and individually, a "**Party**"). For purposes of this Agreement, "**Research Site**" shall include the Research Site who is a signatory to this Agreement and, where appropriate, each signatory of a Network Clinical Trial Agreement with CTNeT.

INTRODUCTION:

The initial operations of CTNeT have been funded by a grant from the Cancer Prevention Research Institute of Texas ("**CPRIT**"), an agency of the State of Texas, that coordinates collaboration and cooperation between academic institutions and community-based oncology practices in the State of Texas to enhance the availability of innovative, efficient, and timely cancer-related clinical research trials for all Texas residents. CTNeT develops clinical research studies for which it serves as the Sponsor, and also contracts with pharmaceutical company sponsors for CTNeT to provide oversight and services for the conduct of such studies at CTNeT Network Sites. This Agreement evidences the agreement between CTNeT and Research Site regarding participation in, and operation of, the CTNeT Network.

ARTICLE 1 - Definitions

1.1 Definitions. Capitalized terms not otherwise defined in the body of this Agreement are set forth on the attached **Exhibit A**, incorporated herein for all purposes.

ARTICLE 2 – Scope, Purposes, Research Personnel

2.1 Governance. The committees of CTNeT include: (a) a Scientific Steering Committee (the "**SSC**"); (b) a Council of Investigators; (c) a Data Safety Monitoring Board, when appropriate; and (d) the CTNeT Central Institutional Review Board (the **"cIRB"**).

2.2 Selection of Studies. The SSC will review and evaluate the scientific merit of proposed protocols to be managed and/or funded by CTNeT. Study concepts for CTNeT will be generated as follows: (a) in response to a request for proposal from CTNeT or CPRIT; (b) direct from a pharmaceutical company; or (c) unsolicited concepts submitted by researchers affiliated with a Research Site.

2.3 Master Agreement. As a "master" form of contract, this Agreement allows Research Site and CTNeT to contract for multiple Studies through the issuance of a series of Work Orders. This Agreement provides general terms relating to Research Site's participation in Studies; the specific terms for participation in a particular Study will be set forth in a mutually agreeable Work Order. Once a Study opportunity is agreed upon in accordance with Paragraph 2.4, Research Site and CTNeT will enter into a Work Order setting forth the specific terms applicable to such Study.

2.4 Study Opportunities. Whenever CTNeT desires to present a Study opportunity to the Network, CTNeT will provide to the Research Site's Lead Investigator, with a copy to the Research Administrator, a Feasibility Survey in the form of a questionnaire to all those Research Sites who have been qualified to participate in this type of Study by the CTNeT site operations and support team. Once presented with a Feasibility Survey, the Research Site shall complete the Feasibility Survey questionnaire (which shall be non-binding) within the time period designated in the Feasibility Survey for response. Failure to timely complete a Feasibility Survey will mean that a Research Site may not be considered for the applicable Study.

2.5 Work Order. If: (a) CTNeT determines that sufficient interest exists for the proposed Study based upon responses received to the Feasibility Surveys; and (b) the pharmaceutical Sponsor (if applicable) and CTNeT reach an acceptable agreement for the Study, then CTNeT will transmit to all qualifying and interested Research Sites a Work Order, the form of which is attached as **Exhibit C**. If Research Site elects to participate in the Study, Research Site will sign and return the Work Order within the time designated in the transmittal of the Work Order. If Research Site has multiple clinic locations that may be bound by Research Site to this Agreement, such sites will be listed on the applicable Work Order. However, each separate location must individually qualify for participation in a Study as determined by CTNeT's operations and site support team and the cIRB. The Work Order will require each Research Site and Principal Investigator to conduct the Study in a manner that enables the Research Site to meet all of its obligations under this Agreement. Failure to timely complete a Work Order will mean that a Research Site may not be considered for the applicable Study.

2.6 CTNeT Subaward Agreement. CTNeT will provide annual funds to Research Site to defray personnel expenses for administrative and research support in connection with Research Site's participation in the Network. Such payment will be reflected in a Subaward Agreement entered into between Research Site and CTNeT.

2.7 Research Personnel. Research Site shall designate employees to serve in the capacities set forth below.

2.7.1 Network Personnel. Each Research Site will designate the following individuals ("Lead Investigator" and "Research Administrator") upon execution of this Agreement, and will communicate such designation to CTNeT prior to the execution of any Work Order. These individuals will serve as liaisons between CTNeT and the Research Site for Network-related issues and questions.

2.7.1.1 Lead Investigator: The "Lead Investigator" is the primary scientific and medical point of contact between CTNeT and the Research Site and will be designated a member of the CTNeT Council of Investigators.

2.7.1.2 Research Administrator: The "Research Administrator" is the individual at Research Site's location who is the primary and initial point of contact for CTNeT at the Research Site regarding general administrative, regulatory, and clinical trial support. The Research Administrator will assist in credentialing, education, site qualification, monitoring, and other duties as assigned by CTNeT, on a part-time basis. Such person(s), and the fees charged to CTNeT, are identified on the signature page of this Agreement.

2.7.2 Study Personnel.

2.7.2.1 Study Chair. For each Study, CTNeT shall name and designate the "Study Chair." The Study Chair is the investigator responsible for the overall conduct of the Study and was responsible for bringing forth the Study concept to CTNeT or, in industry-sponsored Studies, is selected by the Sponsor to represent the Network. The Study Chair is the Study liaison between the industry Sponsor, CTNeT, and the Research Site investigators. If the Study Chair becomes unaffiliated with Research Site prior to the completion of the Study, and the Parties are unable to agree on a replacement within thirty (30) days, CTNeT will have the right to appoint a replacement Study Chair.

2.7.2.2 Principal Investigator. Research Site shall appoint a local Principal Investigator to oversee the Study (each, a "Principal Investigator") in accordance with Applicable Law.

2.7.2.3 Clinical Research Coordinator ("CRC"). The CRC will be trained by CTNeT on the research services required by the Protocol and will manage the Study Data for the Research Site.

2.7.3 Principal Investigator Qualifications. Research Site agrees that all physicians who serve as Principal Investigators in any of the categories listed above will:

(1) Agree to adhere to all applicable good clinical practices in the performance of the Studies; and
(2) Have agreed to assign to Research Site all rights in and to Intellectual

Property (as defined in Section 7.1); and

(3) Have current professional licensure as a physician in the jurisdiction where a Study will be conducted; and

(4) Not have been debarred or restricted from participation in clinical trials by the FDA or the Research Site.

ARTICLE 3 – Study Responsibilities

3.1 The Protocol. Research Site will conduct each Study in accordance with the applicable Protocol and in accordance with all Applicable Law. If any provisions of this Agreement and the Work Order conflict, this Agreement shall control. If a Work Order and a corresponding Protocol conflict, the terms of the Work Order shall govern; provided, however, that if the conflict relates to the protection of subjects, the Protocol shall govern.

3.2 Study Responsibilities of Research Site. Research Site will provide or perform the following in connection with Studies conducted in accordance with a Work Order:

3.2.1 Designate the personnel specified in Section 2.7 above.

3.2.2 Permit monitoring and auditing of the Studies, as further outlined in Section 3.11 below.

3.2.3 Adhere to all Applicable Law and institutional policies of Research Site, as applicable, in the performance of Studies and notify CTNeT of any violations that affect or may affect Research Site's performance of the Study including action taken by the Research Site for such violation.

3.2.4 Require that all Study personnel demonstrate evidence of compliance with good clinical practices and, where applicable, IATA training.

3.2.5 Research Site is an agency of the State of Texas and provides professional liability for its faculty physicians pursuant to The University of Texas System Professional Medical Liability Benefit Plan, under the authority of Section 59, Texas Education Code. Research Site shall ensure the Principal Investigator has and will maintain in force, during the term of this Agreement, adequate professional liability insurance to cover his/her obligations hereunder. Research Site is subject to the provisions of Title 5, Chapter 5, Chapter 101 of the Texas Civil Practice and Remedies Code, and the Research Site's personnel or employees are subject to Title 5, Chapter 104 of the Texas Civil Practice and Remedies Code, also known as the Texas Tort Claims Act. Employees of the Research Sites are provided Worker's Compensation coverage under the self-insuring, self-managed program as authorized by Chapter 503, Section 503.022, Texas Labor Code. This obligation shall survive termination of this Agreement.

3.2.6 Notify CTNeT within twenty-four hours (excluding weekends) or within FDA guidelines of learning of any SAE affecting any subject in a Study.

3.2.7 Ensure that an IRB Reliance Agreement designating the cIRB as the IRB of record in the form attached hereto as **Exhibit B** is executed for each separate clinical location (as applicable) of Research Site.

3.2.8 Report to CTNeT promptly if a Sponsor, governing body of the Research Site, or regulatory agency places a hold or any restriction on a Study or investigator.

3.2.9 Notify CTNeT in the event of an inspection by regulatory authorities at any Research Site relating to a Study and the results of any such inspection in accordance with Section 3.6.

3.3 Study Responsibilities of CTNeT. CTNeT shall provide or perform the following in connection with Studies:

3.3.1 Oversee start-up activities, project management, and overall quality assurance of each Study in accordance with Applicable Law.

3.3.2 Notify Research Site of any changes to the applicable Protocol or informed consent.

3.3.3 Provide an electronic data management system (Medidata Rave) for capture of Study Data.

3.3.4 Maintain performance and quality metrics of all Studies and Research Sites.

3.4 Investigational New Drug Application. When CTNeT is the Sponsor of a Study, CTNeT will obtain and maintain an IND. Otherwise, the IND will be held by the pharmaceutical company Sponsor supplying the Study Agent.

3.5 Debarred Individuals. Research Site hereby represents and certifies to CTNeT, to the best of Research Site's actual knowledge, that Research Site has not used, and will not use, the services of any person debarred under the Generic Drug Enforcement Act of 1992, as amended (**"GDEA"**), in any capacity or connection with any Study. Research Site will notify CTNeT promptly if Research Site becomes aware that any research personnel become debarred under the GDEA during the term of this Agreement.

3.6 Inspections and Audits. Upon reasonable prior notice and during regular business hours, Research Site will permit representatives of CTNeT access to its premises, facilities, records, investigators, and research staff as reasonably required to monitor a Study. Research Site will notify CTNeT as soon as reasonably possible if a Research Site is inspected or scheduled to be inspected by a regulatory agency. Each Research Site and its Principal Investigator will cooperate with representatives of regulatory agencies and CTNeT in the conduct of inspections and audits and will maintain Study Data in a manner reasonably

designed to facilitate such activities. Research Site will promptly forward to CTNeT copies of any inspection findings that Research Site or the Principal Investigator receives from a regulatory agency related to a Study. This section shall survive completion of a Study.

3.7 Notification. The Parties agree, and will require all Research Sites and pharmaceutical company Sponsors (if applicable) to agree, to promptly notify each other upon identifying any aspect of a Study Protocol, including information discovered during site monitoring visits, or Study Results that will or is likely to:

(i) adversely affect the safety, well-being, or medical care of current or former Study subjects; or
(ii) adversely affect the willingness of Study subjects to continue participation in the Study; or
(iii) adversely influence the conduct of the Study, or
(iv) alter an IRB's approval to conduct the Study.

CTNeT shall promptly notify the cIRB of any such information. When Study subjects' safety or medical care is likely to or will be directly and materially affected by such information, then notwithstanding any other provision of this Agreement and applicable Work Order, the Parties will notify Study subjects in accordance with cIRB policies and send Study subjects a written communication about the results.

3.8 Biobank. As set forth in a Protocol, and to the extent authorized by Applicable Law and a subject's informed consent documents (and HIPAA authorization as applicable), Research Site will collect Biological Samples and health information from subjects. Research Site will transfer such Biological Samples to the Biobank in accordance with the detailed instructions of CTNeT and Biobank. Such Biological Samples will be maintained in the Biobank and will be used solely for Protocol purposes, provided, however, that upon the death of a subject, the subject's Biological Samples may be accessed by Research Sites for research purposes. Any such future access and use will be consistent with Applicable Law and Biobank governance policies, which will be consistent with NCI Best Practices for biospecimen research. Research Site agrees that any collection of non-Protocol Biological Samples from any subject will be done in accordance with Applicable Law and the subject's informed consent documents.

ARTICLE 4 - Budget and Compensation

4.1 Budget. CTNeT will provide the financial support for the Study as set forth in the agreed-upon budget included in the Work Order (the **"Budget"**).

4.2 Other Fees. CTNeT may pay Research Site for personnel and other services provided on an administrative basis to support CTNeT's operations in accordance with a separate Subaward Agreement, described in Section 2.6 above.

4.3 Total Payment. Payment of all amounts under this Agreement will be made by CTNeT on a quarterly reimbursement basis in accordance with the Budget.

4.4 Fair Market Value. Each Party acknowledges and agrees that the Budget amounts are consistent with fair market value in light of the professional time and expenses anticipated to be required for the applicable Study. The Parties hereby agree and acknowledge that no part of any Budget is a prohibited payment for the recommending of, or arranging for, the referral of business. Further, no Party will knowingly or intentionally behave in a manner so as to violate the prohibitions against fraud and abuse in connection with Medicare, Medicaid, or other federal and/or state health care programs.

4.5 Study Agent. Any Study Agent furnished pursuant to this Agreement will be used solely in connection with a Study, and Research Site will not charge any person or third-party payor for any such Study Agent whether billed separately or as part of any medical service(s). Research Site will maintain accountability and responsibility for all Study Agents. Research Site will return or destroy all unused Study Agent in accordance with the Protocol.

ARTICLE 5 - Confidentiality

5.1 Human Subject Confidentiality. The Parties agree to comply, and shall require any of the persons or entities participating in a Study, to comply with all Applicable Law governing human subject confidentiality. Research Site will comply with the federal Health Insurance Portability and Accountability Act of 1996 (**"HIPAA"**) and its implementing regulations, as amended from time to time. Each Principal Investigator shall obtain written consent and authorization of each Study subject to permit CTNeT to have access to and use of each subject's Protected Health Information (**"PHI"**), as defined by HIPAA, consistent with the terms of the applicable Work Order; provided that CTNeT shall access and use such PHI only to the extent permitted under such authorization.

5.2 Confidential Information of the Parties. In furtherance of the conduct of a Study, it may be necessary or desirable for the Parties to disclose proprietary, trade secret and/or other confidential information **("Confidential Information"**) to each other. All such Confidential Information shall remain the property of the Party disclosing same. Each Party hereto agrees that any Confidential Information disclosed to it or its employees, agents and contractors, (a) shall be used only in connection with the legitimate purposes of this Agreement or applicable Work Order, (b) shall be disclosed only to those who have a need to know it and are obligated to keep same in confidence, and (c) shall be safeguarded with reasonable care. The Parties shall treat each item of Confidential Information as confidential during the term of this Agreement and for a period of five (5) years after each specific Work Order relative to such Confidential Information terminates. The Parties agree that this Agreement and its terms herein may be subject to the Texas Open Records Act. The Parties further agree that the Protocol is Confidential Information of the Party who wrote the Protocol. Additionally, when requested by the other Party and provided such Confidential Information is not required to perform any obligations under this Agreement, each Party agrees to destroy or return to the requesting Party all copies of Confidential Information of the requesting Party. Notwithstanding the foregoing, each Party may, however, retain one copy of Confidential Information to fulfill its compliance and record keeping obligations, subject to the confidentiality obligations of this Section 5.2.

5.2.1 The foregoing confidentiality obligations shall not apply when, after and to the extent any Confidential Information, that is not also PHI, is disclosed:

(1) is now, or hereafter becomes, generally available to the public through no fault of the receiving Party or its employees, agents or contractors;

(2) was already in the possession of the receiving Party without restriction as to confidentiality at the time of disclosure as evidenced by competent written contemporaneous records, or

(3) is subsequently received by the receiving Party from a third party without restriction and without breaching any confidential obligation between the third party and the disclosing Party hereunder.

(4) is independently developed without use or access to the disclosing Party's Confidential Information.

5.2.2 Notwithstanding any other provisions of this Agreement or any Work Order, Confidential Information may be disclosed:

(i) to the extent necessary to obtain informed consent from patients or human subjects who may wish to enroll in a Study, provided, however, that the Confidential Information will be disclosed only to the extent necessary and Confidential Information will not be provided when answering unsolicited inquiries by telephone or to individuals who are not eligible Study candidates;

(ii) to the extent required by Applicable Law (including, without limitation, the filing and prosecution of patent applications and the disclosure to IRB members and/or regulatory authorities), provided that the Party making such disclosure of the other Party's Confidential Information shall give the other Party as much advance notice as is reasonably practicable of same and shall request confidential treatment of such disclosure from the recipient thereof as may be afforded by Applicable Law.

(iii) for the safety or well-being of a human subject.

5.2.3 If and when Confidential Information is no longer confidential as a result of one of the exclusions in Section 5.2.1 above, a Party will not be restricted with respect to its use or disclosure of such information. Disclosures permitted by Section 5.2.2 and Section 7.3 below shall not affect the confidentiality of such information for other purposes.

ARTICLE 6 - Ownership of Documents and Data

6.1 Data Ownership. Research Site owns all Source Documents and Study Results. The Sponsor owns all Study Data. CTNeT, the Sponsor (if separate) and Research Site may freely use their own data subject to human subject consent and cIRB approval. In addition, Research Site may freely use Study Data after the first multicenter publication is published or the Sponsor waives its right to a multicenter publication.

ARTICLE 7 - Intellectual Property

7.1 Intellectual Property Defined. For purposes of this Agreement and its associated Work Orders, **"Intellectual Property"** means any discovery or invention resulting from or created or developed under a specific Study.

7.2 Background Rights. The respective intellectual property of CTNeT and Research Site in existence as of the Effective Date or created or developed outside the scope of this Agreement or associated Work Orders are the separate property of CTNeT and Research Site and are not affected by this Agreement, and neither Party shall have any claims to or rights in such separate intellectual property of the other Party. None of Research Site, Research Site's employees, agents, or contractors shall acquire any rights, including any intellectual property rights, with respect to a Study Agent as a result of participation in a Study except as set forth in this Agreement. Research Site hereby represents and certifies that it has not entered, and will not enter, into any contractual agreement or relationship which would in any way conflict with or compromise CTNeT's or any third-party Sponsor's proprietary interest in, or rights to, any Intellectual Property.

7.3 Research Site's Obligation to Disclose. Research Site and its employees, agents and contractors shall promptly and routinely disclose to CTNeT any Intellectual Property.

7.4 Discoveries. Any Intellectual Property created solely by Research Site or the clinic locations under Research Site's control will be the sole property of Research Site ("Research Site Inventions"). Intellectual Property discovered jointly by Principal Investigators from separate Research Sites or by one or more Principal Investigators and the Sponsor will be jointly owned ("Joint Inventions"), and inventorship will be determined in accordance with United States patent law.

7.4.1 Investigator-Initiated Studies. For any Study where the Protocol was written by a Principal Investigator (an "Investigator-Initiated Study"), the following provisions shall apply:

7.4.1.1 Joint Inventions will be subject to the following terms and conditions: (1) the owners of the Joint Inventions shall meet and negotiate in good faith one or more definitive agreements ("Definitive Agreement(s)") to set forth the specific term and conditions that shall apply to joint ownership and protection efforts for the Joint Inventions, including without limitation, terms and conditions to govern any use or commercialization of the Joint Inventions as well as terms to govern the protection, prosecution and maintenance of proprietary rights in and to same. In the event the owners of the Joint Inventions shall be unable to reach a Definitive Agreement within a one hundred and eighty (180) day period (unless extended by mutual agreement of the owners), such owners agree to submit the open issues to mediation, and (2) no such owner shall independently license or commercialize any Joint Invention until such time that the Definitive Agreement is finalized. Provided, however, if all open issues

are not resolved by mediation within 180 days after submission thereof, the owners of the Joint Invention may use all rights to which they are entitled under applicable patent law.

7.4.2 Sponsor-Initiated Studies. For any Study where CTNeT or a pharmaceutical company Sponsor wrote the Protocol (a "Sponsor-Initiated Study"), the following provisions shall apply:

7.4.2.1 All rights, title and interests in and to any Intellectual Property shall belong to the Sponsor.

7.4.2.2 Research Site agrees to assign to the Sponsor, at the written request of the Sponsor, the sole and exclusive ownership all Intellectual Property, upon payment of all costs by the Sponsor incurred by Research Site in the filing, prosecution, issuance and/or maintenance of any patent application or patent issuing thereon prior to the date of such assignment. Further prosecution, defense, maintenance and enforcement of any such application(s) and patent(s), as well as the costs thereof, shall thereafter be the sole responsibility of the Sponsor.

7.4.2.3 Research Site will reasonably assist the Sponsor, at the Sponsor's expense, in executing any documents or other instruments reasonably appropriate for vesting or confirming ownership of Intellectual Property in the Sponsor and will provide reasonable cooperation to the Sponsor, at the Sponsor's expense, in prosecuting such patent applications.

7.4.2.4 Notwithstanding the assignment of any Intellectual Property to a Sponsor, Research Site shall have and retain the perpetual, irrevocable, no-cost right to use any Intellectual Property for internal non-commercial research, academic and patient care purposes.

7.5 CTNeT-funded Studies. For any Study funded by CTNeT, CTNeT shall retain a non-exclusive license to use any Intellectual Property rights resulting from or otherwise related to such Study for non-commercial activities (e.g., education and research).

7.6 Publication; Release of Information. For purposes of this Section 7.6, references to CTNeT include a pharmaceutical sponsor, if applicable.

7.6.1 Timing. The Parties anticipate that all Studies will be multi-center studies, and the first published work will be a joint publication. Research Site and/or its Principal Investigators may freely publish and disseminate the Study Results, subject to the terms of this Section 7.6. If no multi-center publication has been made by within one (1) year from the date of the completion or termination of the Study, then Research Site and/or its Principal Investigator may individually publish its Study Results.

7.6.2 Review; Intellectual Property. Research Site and/or the Principal Investigator shall provide CTNeT a copy of the manuscript prepared for publication hereunder and/or a reasonably detailed summary or abstract of any other oral presentation or written publication not less than thirty (30) days prior to their submission to a scientific journal or presentation at scientific meeting. CTNeT shall complete its review within thirty (30) days after receipt of any proposed publication. CTNeT may comment on, but may not make any editorial changes to, the results and conclusions set forth in any publication or presentation hereunder. If CTNeT identifies any of its Confidential Information (as defined above) contained in any such publication or presentation, Research Site and/or the Principal Investigator will delete such Confidential Information, provided, however, that the Confidential Information of CTNeT will not be deemed to include any of the Study Results such that Research Site and Principal Investigator will not be required to delete Study Results from any publication. If CTNeT believes that any proposed publication contains any patentable subject matter, the disclosure of such proposed publication to any third party shall be delayed for up to six (6) months to permit the filing of a patent application.

7.6.3 Authorship. Inclusion of Research Site and/or Principal Investigators in the authorship of any joint publication will be based on substantial contribution to Study design, Study Results, drafting and/or critically revising any manuscript(s) prepared in connection with a Study. The authorship and contents of any publication by Research Site alone shall be determined solely by Research Site and/or the Principal Investigator. All publications shall acknowledge CTNeT as the Sponsor, when applicable, and participation in the Network. For example, "This Study was performed by Research Site as a member of the Statewide Clinical Trials Network of Texas (CTNeT) and acknowledges the contributions of CTNeT."

7.7 Use of Names. No Party shall use the other Party's name without the prior written permission of such other Party, which will not be unreasonably withheld. Research Site specifically consents to the inclusion of Research Site's name as a member of the Network on the CTNeT website during the term of this Agreement. CTNeT also reserves the right to disseminate reprints of scientific, medical and other published articles relating to a Study including reprints that disclose the name of Research Site. CTNeT will be responsible for adding the Study to the clinical trials registry at www.clinicaltrials.gov. Research Site may list CTNeT Studies on Research Site's website.

ARTICLE 8 - Termination

8.1 Term. This Agreement shall continue for ten (10) years and all Work Orders have expired or terminated, unless terminated earlier as herein provided. The term of each Work Order is defined in such Work Order.

8.2 Termination. This Agreement may be terminated by the Parties prior to the expiration of its term upon written notice if any of the following conditions occur:

8.2.1 By either Party, without cause, upon sixty (60) days prior written notice to the other Party;

8.2.2 By the non-breaching Party, in the event of the other Party's failure to remedy any material breach of this Agreement, within thirty (30) days of being notified in writing of the breach by the non-breaching Party; or

8.2.3 By mutual written agreement.

8.3 Effect of Termination.

8.3.1 Immediately upon receipt of a notice of termination of this Agreement pursuant to Section 8.2 above, or if any Study is terminated in accordance with the terms of a Work Order, Research Site shall: (i) stop accepting human subjects into any Study, (ii) cease use of any Study Agent to the extent medically safe for Study subjects; and (iii) undertake all reasonable efforts to minimize further costs.

8.3.2 In the event any Study subject is still involved in a Study when notice of termination is provided by any Party, Research Site and CTNeT shall work together in good faith to resolve any open issues relating to such subject(s) with due regard to the health and safety of such subject, which obligation shall survive the termination of this Agreement.

8.3.3 CTNeT will pay Research Site for: (i) all payments due as of the effective date of termination, (ii) any further requested Study Data including additional CRF processing, in accordance with the applicable Budget, and (iii) all reasonable expenses incurred by Research Site in connection with the closing of the Study.

ARTICLE 9 - Indemnification and Insurance

9.1 Indemnification by CTNeT. CTNeT will indemnify, defend and hold harmless The University of Texas System and its Board of Regents, Research Site, Research Site's Principal Investigators, and Research Site's directors, officers, subcontractors, agents and employees (the **"Research Site Indemnitees"**) from any and all liability resulting from CTNeT's breach of this Agreement or a Work Order or CTNeT's use of the Study Data or Study Results, so long as such liability is not caused by (a) the negligent, reckless or willful acts of any of the Research Site Indemnitees, or (b) Research Site's material failure to comply with the Protocol or any written instructions of the Sponsor regarding the Study and received by Research Site, excluding actions taken to protect patient welfare, or (c) the failure by the Research Site Indemnitee to comply with Applicable Law.

9.2 Indemnification for Use of Study Agent. CTNeT will contractually obligate the pharmaceutical company providing the Study Agent to indemnify, defend and hold harmless the Research Site Indemnitees from any and all liability resulting from the use of the Study Agent, the Study Data, or Study Results, so long as such liability is not caused by (a) the negligent, reckless or willful acts of any of the Research Site Indemnitees, or (b) Research

Site's material failure to comply with the Protocol or any written instructions of the Sponsor regarding the Study and received by Research Site, excluding actions taken to protect patient welfare, or (c) the failure by the Research Site Indemnitee to comply with Applicable Law.

9.3 Indemnification by Research Site. To the extent authorized by the Texas constitution and the laws of the State of Texas, Research Site will indemnify, defend and hold harmless CTNeT and its directors, officers, subcontractors, employees and agents (the "**CTNeT Indemnitees**") and the Sponsor and its directors, officers, subcontractors, employees and agents (the "**Sponsor Indemnitees**") from any and all liability resulting from (a) the negligent acts or omissions of Research Site or its clinic locations, its Principal Investigator(s) or any of their respective agents or employees, or (b) the material failure by Research Site or its clinic locations, their Principal Investigator or any of their respective agents or employees, to comply with Applicable Law or this Agreement or the applicable Work Order, provided, however, that such indemnity shall not apply to claims arising out of the negligence or willful malfeasance of a CTNeT Indemnitee or a Sponsor Indemnitee or any person not subject to Research Site's supervision or control.

9.4 Mutual Obligations. If a claim for indemnification is made under Section 9.1, 9.2, or 9.3 above, the Parties shall cooperate with each other in the investigation and disposition of such claim; provided, however, that nothing herein shall require either Party to disclose any documents, records or communication that are protected under the attorney-client privilege or the attorney work-product doctrine. Each indemnitor's agreement to indemnify and hold harmless is conditioned on the applicable indemnitee: (i) providing adequate written notice to the indemnitor of the claim, demand, or action; (ii) permitting the indemnitor to assume full responsibility for investigation, preparation and defense; and (iii) not compromising or settling any claim or demand without the indemnitor's prior written consent. The indemnitee shall cooperate with all investigations relating to the claim, at the cost of the indemnitor. This Article 9 is subject to the statutory duties of the Texas Attorney General for Research Sites who are an agency of the State of Texas.

9.5 Injury Compensation. CTNeT shall endeavor to obligate the pharmaceutical company or companies providing the Study Agent to pay reasonable medical and hospital expenses associated with the treatment of any illness or injury of a Study subject deemed related to administration of the Study Agent. Research Site and the Principal Investigators agree to state in any informed consent form that CTNeT has not agreed to compensate for research related injuries.

9.6 Reporting Obligations. CTNeT shall ensure that each will keep the other Party and/or pharmaceutical company (as the case may be) currently informed about SAEs and the safe use of the study Agent as required under 21 CFR 312.55. CTNeT will require that the Sponsor shall comply with its reporting obligations under 21 CFR 312.66.

ARTICLE 10 - Representations and Certifications and Warranties; Grant Requirements

10.1 Research Site Representations and Certifications. Research Site represents and certifies to CTNeT that:

10.1.1 Research Site is a duly organized and validly existing agency of the State of Texas, under the laws of the State of Texas.

10.1.2 Research Site has the power and authority to execute and deliver this Agreement on behalf of itself and Research Site's practice sites, if any, and to perform its obligations hereunder, and Research Site's execution and delivery of, and performance its obligations under, this Agreement have been duly and validly authorized by all necessary action of Research Site.

10.1.3 Research Site has personnel, equipment, experience and expertise sufficient in quality and quantity to carry out its obligations under this Agreement and shall do so (i) in a responsible and timely manner commensurate with the professional standards generally applicable to the conduct and management of clinical drug studies in the United States, and (ii) in accordance with Applicable Law.

10.1.4 Research Site shall have no financial interests and/or arrangements with any particular Sponsor that will require disclosure to FDA in accordance with 21 CFR Part 54.

10.1.5 Research Site has developed a reasonable business interruption and disaster recovery program and shall use reasonable efforts to assess and reduce the extent to which Research Site's hardware, software and embedded systems may be susceptible to errors or failures in various crises (or force majeure) situations. If any Study Data delivered by Research Site to CTNeT is materially inaccurate as a result of such errors or failures, Research Site will take reasonable steps necessary to rectify such errors by Research Site within mutually agreeable time frames.

10.1.6 If Research Site uses electronic systems for creating, modifying, maintaining, archiving, retrieving or transmitting any records, including Study Data that are required by, or subject to inspection by an applicable regulatory authority (including the FDA), Research Site represents and certifies that Research Site has developed standard operating procedures and systems that are compliant with Research Site's reasonable understanding of 21 CFR Part 11. Research Site further represents and certifies to CTNeT that, in order to comply with 21 CFR Part 11, it will not use any electronic signatures on any documents required by, submitted to, or supporting a submission to the FDA unless Research Site, as applicable, has certified to the FDA that it intends such electronic signatures to be the legally binding equivalent of a hand-written signature.

10.1.7 To the best of its knowledge at the time of signature hereto, neither the

execution and delivery of this Agreement nor Research Site's performance of its obligations hereunder will violate or breach, or otherwise constitute or give rise to a default under, the terms or provisions of any contract, commitment or other obligation to which Research Site is a party, or violate or result in a breach of or constitute a default under any judgment, order, decree, rule or regulation of any court or governmental agency to which Research Site is subject.

10.2 CTNeT Representations and Warranties. CTNeT represents and warrants to Research Site that:

10.2.1 CTNeT is a duly incorporated, validly existing non-profit corporation under the laws of the State of Texas;

10.2.2 CTNeT has the corporate power and authority to execute and deliver this Agreement and to perform its obligations hereunder, and CTNeT's execution and delivery of, and performance of its obligations under, this Agreement have been duly and validly authorized by all necessary corporate action by CTNeT.

10.2.3 Neither the execution and delivery of this Agreement nor CTNeT's performance of its obligations hereunder will violate or breach, or otherwise constitute or give rise to a default under, the terms or provisions of any material contract, commitment or other obligation to which CTNeT is a party, or violate or result in a breach of or constitute a default under any judgment, order, decree, rule or regulation of any court or governmental agency to which CTNeT is subject.

10.2.4 CTNeT shall have no financial interests and/or arrangements with any Sponsor that will require disclosure to FDA in accordance with 21 CFR Part 54;

10.2.5 CTNeT has developed a reasonable business interruption and disaster recovery program and is executing such program to assess and reduce to the extent to which CTNeT's hardware, software and embedded systems may be susceptible to errors or failures in various crises (or force majeure) situations that would affect the Network.

10.3 Grant Awards. As a recipient of a grant from CPRIT or other grantor, CTNeT is required to comply with the terms of its granting contract from CPRIT or such other grantor. Research Site agrees to reasonably cooperate with CTNeT's compliance requirements, including providing documentation necessary to evidence compliance with the terms of the applicable grant. Such documentation may include: (1) a statement of the progress made on any particular Study; (2) an inventory of any equipment purchased with CTNeT funding; and (3) a statement of any discoveries made during a Study.

ARTICLE 11 – Miscellaneous

11.1 Effective Date. This Agreement will be considered accepted, approved, and otherwise effective as of the Effective Date, regardless of when the signature of each Party is

affixed in the space provided below.

11.2 Counterparts. This Agreement may be executed in counterparts with the same effect as if all Parties had signed the same document. All such counterparts shall be deemed an original, shall be construed together and shall constitute one and the same document.

11.3 Waiver. Waiver from time to time by either Party of any of its rights or failure to exercise any remedy under this Agreement shall not operate or be construed as a continuing waiver of any of such Party's rights or remedies provided in this Agreement.

11.4 Notices. Any notice, demand, waiver, consent, approval or other communication that is required or permitted to be given to any Party hereunder shall be in writing and shall be deemed given, if delivered to the Party personally, at the time when delivered; if sent to the Party by facsimile, upon confirmation of transmission; if sent to the Party by electronic means, upon confirmation of receipt; or if by registered or certified mail, with postage and registration or certification fees thereon prepaid, on the third day after dispatch; or by a nationally recognized overnight courier company (providing receipt of delivery), on the next day after timely deposit with such courier. addressed to the Party at its address set forth below or to such other address as the receiving Party may notify the sending Party in writing:

To Research Site: As set forth on Exhibit D.

To CTNeT: 5080 Spectrum Drive, Suite 600W
Dallas, Texas 75001
Attention: Chief Operating Officer

With a copy to: Holly J. Powers
Jameson & Powers, P.C.
17110 Dallas Parkway, Suite 210
Dallas, Texas 75248

11.5 Survivability. The terms and conditions of Articles 4, 5, 6, 7, 8 and 9 and Sections 3.2, 3.3, 3.4, 10.3, and 11.9 of this Agreement shall survive the expiration or earlier termination of this Agreement.

11.6 Entire Agreement. This Agreement constitutes the sole, full and complete agreement by and between the Parties with regard to the subject of this Agreement, and no amendments, changes, additions, deletions, or modifications of this Agreement will be valid unless reduced to writing and duly signed by the Parties. All prior and contemporaneous agreements between the Parties, including the Network Participation Understanding, are merged into this Agreement.

11.7 Independent Contractors. Research Site, its Principal Investigators, subcontractors, agents and employees are acting in the capacity of independent contractors hereunder and not as employees or agents of CTNeT. This Agreement shall not, and is not

intended to, make the Parties partners, joint venturers, or agents of one another. No Party shall have the power to bind or obligate any other Party.

11.8 Assignment. Neither Party may assign this Agreement without the prior written consent of the non-assigning Party.

11.9 Dispute Resolution

11.9.1 The appropriate contract managers or other designated individuals representing the Parties shall meet and attempt in good faith to settle any dispute, claim or controversy arising out of or relating to the interpretation, performance or breach of this Agreement (the **"Dispute").** Either Party seeking to resolve the Dispute shall send notice to the other Party, and a meeting shall be held between the managers or designated representatives of both Parties within ten (10) business days after the date of such notice. However, if the contract managers fail to resolve the Dispute within five (5) business days after such initial meeting (the **"Initial Dispute Resolution Period"**), then such Dispute shall be referred for resolution to designated senior executives of both Parties who have the authority to settle the Dispute but who are not directly involved in the Dispute. At the conclusion of the Initial Dispute Resolution Period, the Party invoking this dispute resolution procedure shall give written notice to the other Party and the receiving Party shall, within ten (10) business days submit a written response. The notice and response shall include: (i) a statement of that Party's position and a summary of evidence and arguments supporting its position, and (ii) the name and title of the senior executive who shall represent such Party. The designated senior executives of each Party shall attempt in good faith to settle such Dispute within thirty (30) days from the date the disputing Party receives the above written response (the **"Secondary Dispute Resolution Period"**).

11.9.2 If the Parties are unable to resolve all issues within the Secondary Dispute Resolution Period, the Parties shall be free to resolve any such issues through appropriate legal and/or equitable measures. Notwithstanding the foregoing, nothing in this paragraph shall be construed to waive any rights or timely performance of any obligations existing under this Agreement.

11.10 Governing Law. This Agreement shall be governed by the laws of the State of Texas.

11.11 Conflict. If any portion of this Agreement is found by any court or agency with jurisdiction over the subject matter hereof not to be in compliance with any Applicable Law, that portion of the Agreement shall be deemed void unless, within thirty (30) days after such determination, the Parties have retroactively amended and reformed the Agreement as necessary to comply, and the Parties shall thereafter cooperate in taking such actions as are necessary to secure compliance with such Applicable Law.

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed, by duly authorized representatives, as of the last date written below.

Research Site:
The University of Texas Health Science Center at San Antonio

By: _____
Print Name: Jane A Youngers
Title: Assistant Vice President for Research

Statewide Clinical Trials Network of Texas

By: _____
Print Name: Patricia A. Winger
Title: Chief Operating Officer

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed, by duly authorized representatives, as of the last date written below.

Research Site:
The University of Texas Health Science Center at Houston

By: _____
Print Name: _____
Title: _____
Jodi S. Ogden, MBA, CRA
Executive Director
Sponsored Projects Administration

Statewide Clinical Trials Network of Texas

By: _____
Print Name: Patricia A. Winger
Title: Chief Operating Officer

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed, by duly authorized representatives, as of the last date written below.

Research Site:
The University of Texas Health Science Center at Tyler

By: _____
Print Name: Joseph F. Woelkers
Title: Sr. Vice President

Statewide Clinical Trials Network of Texas

By: _____
Print Name: Patricia A. Winger
Title: Chief Operating Officer

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed, by duly authorized representatives, as of the last date written below.

Research Site:
The University of Texas M. D. Anderson Cancer Center

By: _____ 8/16/12
Print Name: Wesley Harrott
Title: Executive Director
Research Administration

Reviewed and Approved by
UTMDACC Legal Services for
UTMDACC Signature:
for RR 8/15/12

Statewide Clinical Trials Network of Texas

By: _____
Print Name: Patricia A. Winger
Title: Chief Operating Officer

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed, by duly authorized representatives, as of the last date written below.

Research Site:
The University of Texas Medical Branch at Galveston

By: Susan E Ramsey 8/16/12
Print Name: Susan E. Ramsey, CRA
Title: Manager of Research Operations

Statewide Clinical Trials Network of Texas

By: Patricia Winger
Print Name: Patricia A. Winger
Title: Chief Operating Officer

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed, by duly authorized representatives, as of the last date written below.

Research Site:
The University of Texas Southwestern Medical Center

By: _____
Print Name: Angela R. Charboneau Wishon, J.D.
Title: Vice President for Research Administration

Statewide Clinical Trials Network of Texas

By: _____
Print Name: Patricia A. Winger
Title: Chief Operating Officer

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed, by duly authorized representatives, as of the last date written below.

Research Site:
The University of Texas at Austin

By: _____
Print Name: Bill Catlett
Title: Director, Office of Industry Engagement

Statewide Clinical Trials Network of Texas

By: _____
Print Name: Patricia A. Winger
Title: Chief Operating Officer

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed, by duly authorized representatives, as of the last date written below.

Research Site:
The University of Texas at El Paso

By: 8/16/12
Print Name: Roberto A. Osegueda
Title: Vice President for Research

Statewide Clinical Trials Network of Texas

By:
Print Name: Patricia A. Winger
Title: Chief Operating Officer

EXHIBIT A

Definitions

"AAHRPP" means the association for Accreditation of Human Research Protection Program.

"**Applicable Law**" means all local, state and federal statutes and regulations that are relevant and applicable to the conduct of research on human subjects.

"Biobank" shall mean the CTNeT biorepository located at the Texas Cancer Research Biobank in Houston, Texas.

"Biological Samples" means any material, including without limitation, blood, serum, fluid and tissue biopsy samples, collected from Study subjects and any tangible material directly or indirectly derived there from.

"**Case Report Form**" (**CRF)** means case report forms submitted to a Sponsor in compliance with the Protocol and Work Order.

"cIRB" is the central Institutional Review Board (IRB) designated by CTNeT to oversee all clinical trials of CTNeT. The cIRB will seek accreditation from AAHRPP or other accrediting organization for human research protection programs.

"**Confidential Information**" has the meaning set forth in Section 5.2 of this Agreement.

"**Council of Investigators**" means the CTNeT committee whose members are Lead Investigators.

"Clinical Research Coordinator" (CRC) shall have the meaning set forth in Section 2.7.2.3 of this Agreement.

"**FDA**" means the federal Food and Drug Administration or any successor agency of the federal government that has been assigned the regulatory functions now exercised by the federal Food and Drug Administration.

"**Feasibility Survey**" means a synopsis of a proposed Study, noting non-standard of care assessments, accrual estimates and an anticipated per-patient budget as described in Section 2.4 of this Agreement.

"**GDEA**" has the meaning set forth in Section 3.5 of this Agreement.

"**HIPAA**" has the meaning set forth in Section 5.1 of this Agreement.

"**IATA**" means International Air Transport Association, which prescribes standards for packaging and shipping Biological Samples.

"**IND**" means an Investigational New Drug Application, which is submitted to the FDA to receive approval to conduct experimental clinical trials.

"**Initial Dispute Resolution Period**" has the meaning set forth in Section 11.9 (a) of this Agreement.

"Intellectual Property" has the meaning set forth in Section 7.1 of this Agreement.

"Investigator-Initiated Study" means a Study where the Protocol was written by a Principal Investigator as further described in Section 7.4.1 of this Agreement.

"**IRB"** means an institutional review board responsible for reviewing research involving human subjects as required by federal law.

"**IRB Reliance Agreement**" has the meaning set forth in Section 3.2.7 of this Agreement.

"Lead Investigator" has the meaning set forth in Section 2.7.1.1 of this Agreement.

"**Network**" means those academic or research institutions and community-based oncology practices in the State of Texas (each referred to as a "**Research Site**") who have signed this Network Clinical Trial Agreement.

Protected Health Information ("PHI") means protected health information, as referenced in Section 5.1, and includes patient-identifying data from medical records or attached to patient specimens, to be obtained prospectively or from stored medical records or specimens, that can be linked to individual Study subjects, either directly or indirectly through codes and further defined by HIPAA.

"Principal Investigator" is described in Section 2.7.2.2 of this Agreement.

"Protocol" means the document describing the scientific investigation and purpose of a clinical research trial.

"Research Administrator" has the meaning set forth in Section 2.7.1.2 of this Agreement.

"Research Site" shall have the meaning set forth in the first paragraph of this Agreement.

"**Secondary Dispute Resolution Period**" has the meaning set forth in Section 11.9 (a) of this Agreement.

"Serious Adverse Event" as defined in 21 C.F.R. 312.32, is an adverse event that results in: (1) death or is life-threatening; (2) hospitalization, or prolongs hospitalization;

(3) a significant incapacity or substantial disruption of normal life functions; (4) a congenital anomaly/birth defect; (5) an important medical event such that medical or surgical intervention is required to prevent one of the above outcomes.

"Source Documents" means all original human subject medical documents and records, specifically excluding CRFs.

"Sponsor" means an organization or individual who assumes legal responsibility for supervising or overseeing clinical trials with investigational drugs, pursuant to an executed Work Order.

"Sponsor-initiated Study" means a Study where the Protocol was written by CTNeT or a pharmaceutical company, as further described in Section 7.4.2 of this Agreement.

"**Study**" means CTNeT-managed research involving the use one or more Study Agent(s) for the treatment of cancer in a subject, as described in an executed Work Order.

"Study Agent" means one or more specific materials or devices for use in a particular Study related thereto for the treatment of cancer in subjects, as described in Section 4.5 of this Agreement.

"Study Chair" has the meaning set forth in Section 2.7.2.1 of this Agreement.

"Study Data" means human subject lab test results, case report forms and all other human subject information collected from a Study per the Protocol, Agreement or other written instruction by Sponsor, excluding Source Documents. Specifically excludes Study Results.

"Study Results" means (a) research data, (b) results of Research Site's investigative findings, and (c) research results created under and as a result of a Study, specifically excluding Study Data.

"Subaward Agreement" means that document executed in connection with this Agreement between Research Site and CTNeT, and all amendments thereto, that addresses funds granted to Research Site by CTNeT for certain administrative and research support, as referenced in Section 2.6.

"**Work Order**" means the Study-specific Clinical Study Work Order entered into between Research Site and CTNeT relating to a particular Study, pursuant to Sections 2.3 and 2.5 of the Agreement.

EXHIBIT B

FORM OF INSTITUTIONAL REVIEW BOARD (IRB) RELIANCE AGREEMENT

IRB RELIANCE AGREEMENT
AND
MEMORANDUM OF UNDERSTANDING (MOU)

1) PURPOSE:

This Reliance Agreement and Memorandum of Understanding ("MOU") sets forth the agreement between participating UT Institutions concerning the use of the Central Institutional Review Board (cIRB) of the Statewide Clinical Trials Network of Texas (CTNeT) for research that will be conducted by investigators at those institutions for all studies sponsored or supported in whole or in part by CTNeT. The initial participating institutions are listed in Section 3. Additional institutions may participate by executing the MOU and appending information on affiliated institutions as an additional Appendix.

2) SCOPE:

The signatory officials agree that organizations executing this MOU may rely on CTNeT's cIRB for review, approval and continuing oversight of human subject research as defined by federal regulations for CTNeT-funded or supported studies where the participating institution is a "Research Site" as defined in the Network Clinical Trial Agreement (the "Network Agreement") signed by CTNeT and such participating institution.

3) Names of Participating Organizations, Organization Number, Federalwide Assurance Number (FWA) and IRB Registration Number(s)

University of Texas at Arlington (UTA) – IORG0001464
Federalwide Assurance #: FWA00001762
IRB Registration #: IRB00005768

University of Texas at Austin (UTAustin) – IORG0000091
Federalwide Assurance #: FWA00002030
IRB Registration #: IRB00000130

University of Texas Brownsville - IORG0002687
Federalwide Assurance #: FWA00004472
IRB Registration #: IRB00003261

University of Texas at Dallas (UTD) – IORG0000054
Federalwide Assurance #: FWA00005412
IRB Registration #: IRB00000076

University of Texas at El Paso (UTEP) – IORG0000191
Federalwide Assurance #: FWA00001224
IRB Registration #: 00000311

University of Texas Pan American – IORG0001139
Federalwide Assurance #: FWA00000805
IRB Registration #: IRB00001540
University of Texas Pan American – IORG0005915
Federalwide Assurance #: FWA00014669
IRB Registration #: IRB00007130

University of Texas San Antonio (UTSA) – IORG0002490
Federalwide Assurance #: FWA00003861
IRB Registration #: IRB00003048

University of Texas Tyler – IORG0004460
Federalwide Assurance #: FWA00009775
IRB Registration #: IRB00005292

University of Texas Southwestern (UT Southwestern) – IORG0000638
Federalwide Assurance #: FWA00005087
IRB Registration #: IRB00000974, IRB00000975, IRB00000976, IRB00003142

University of Texas Medical Branch (UTMB) – IORG0000137
Federalwide Assurance #: FWA00002729
IRB Registration #: IRB00000757, IRB00000232

University of Texas Health Science Center at Houston (UTHEALTH) – IORG0000188
Federalwide Assurance #: FWA00000667
IRB Registration #: IRB00000308, IRB00003763, IRB00004604

University of Texas Health Science Center at San Antonio (UTHSCSA) - IORG0000312
Federalwide Assurance #: FWA00005928
IRB Registration #: IRB00000553, IRB00002691, IRB00002692

University of Texas Health Science Center Tyler – IORG0000370
Federalwide Assurance #: FWA000000003494
IRB Registration #: IRB00000627, IRB00002921

University of Texas M.D. Anderson Cancer Center – IORG0000083
Federalwide Assurance #: FWA00000363
IRB Registration #: IRB00000121, IRB00002203, IRB00003869, IRB00005015, IRB00006023

4) Name of other Institutions that may in turn rely on Participating Institutions (Research Sites):

Institutions affiliated with the Participating Organizations are listed in Appendix 1.1.

5) COMPLIANCE WITH OFFICE OF HUMAN RESEARCH PROTECTION'S GUIDANCE

This MOU meets the federal requirements for designation of another institution's IRB as the Reviewing IRB, as set forth in guidance issued by the Office for Human Research Protections' (OHRP), Terms of the Federalwide Assurance, March 20, 2002.

6) AUTHORITY:

A. 45 CFR Part 46 Subparts A (Common Rule), B, C & D
B. 21 CFR Parts 50, 56, 312, and 812
C. 45 CFR Parts 46.160 & 164 (HIPAA Privacy Rule)

7) DEFINITIONS

a) **Affiliated Institutions –** an institution relying on CTNeT's cIRB and formally agreeing to participate in this reliance agreement, as evidenced by its inclusion in Appendix 1.1.
b) **Human Research Protection Program (HRPP)**-- encompasses the entities within the Participating Organization that contribute to the mission to protect the rights and welfare of participants who take part in human subject research,

including but not limited to the institutional officials, IRB, and research staff.

c) **Human Subject Research** – Activities that meet the United States Department of Health and Human Services (DHHS) definition of research set forth in 45 CFR § 46.102(d) and involve human subjects as set forth in 45 CFR § 46.102(f), or activities that meet the United States Food and Drug Administration (FDA) definitions of research/clinical investigation set forth at 21 CFR § 50.3(c) and § 56.102(c) that involve human subjects as set forth at 21 CFR § 50.3(g), § 103(e), § 312.3(b) and § 812.3(p).

d) **Institutional Official** – The Institutional Official (IO) who is the signatory on the FWA filed with OHRP to assure compliance with regulations governing protection of human subjects. OHRP requires the Institutional Official to be a high-level official who has the authority to represent the institution named in the FWA.

e) **Participating Organizations –** all UT Institutions participating in this reliance agreement and that are signatories to this MOU.

f) **Relying Organization** – a Participating Organization that agrees to rely on another Participating Organization's IRB for a specific study.

g) **Reviewing IRB** – the CTNeT cIRB that agrees to serve as the IRB of record for a specific study for one or more of the other Participating Organizations.

8) BACKGROUND:

Each Participating Organization shall maintain a separate, active FWA with OHRP. Each Organization recognizes OHRP's current policy guidance on defining when an institution is engaged in research covered by the Common Rule and each institution's FWA. The review and continuing oversight performed by the Reviewing IRB will meet the human subject protection requirements of each Relying Organization's OHRP-approved FWA. Relevant minutes of IRB meetings will be made available to the Relying Organizations. The Relying Organization remains responsible for ensuring compliance with the Reviewing IRB's determinations and with the terms of its OHRP-approved FWA. This document must be kept on file at all Relying Organizations and provided to OHRP upon request.

9) RIGHTS, DUTIES, AND RESPONSIBILITIES OF THE REVIEWING IRB:

a) The Reviewing IRB will establish and follow its written policies and procedures as required, to comply with federal and state laws pertaining to the protection of human participants in research.

b) The Reviewing IRB shall ensure that the Relying Organization has agreed to rely on the Reviewing IRB for a specific study. The Reviewing IRB will consider

conflicts of interest using its local Conflict of Interest policy. The Reviewing IRB will include the Conflict of Interest management plan applicable to investigators from Relying Organizations in the study approval.

c) The Reviewing IRB will notify the Relying Organization of any unanticipated problems involving risks to subjects or others, serious or continuing non-compliance with the regulations or the requirements or determinations of the IRB, and termination or suspension of IRB approval of research and collaborate with the Relying Organization to draft a joint notification letter to OHRP and FDA (as applicable).
d) The Reviewing IRB will make its records, including any relevant communications with investigators, available upon request to appropriate officials at the Relying Organization and to regulatory and accrediting entities.
e) The Reviewing IRB and Relying Organization will develop a mutually agreeable process to ensure that the Reviewing IRB communicates to the Relying Organization all initial approvals, disapprovals and/or closures of the proposed research.
f) The Reviewing IRB may require the Relying Organization to conduct a monitoring visit and/or require the Relying Organization to observe the consent process at the Relying Organization.
g) The Reviewing IRB will collaborate with the Relying Organization on the investigation, management, and reporting to regulatory agencies and appropriate institutional officials of serious or continuing non-compliance, unanticipated problems involving risks to subjects or others, and suspensions and terminations of IRB approval.
h) Right to Terminate Serving as the IRB of Record – After initial approval of a study, the Reviewing IRB may terminate serving as the IRB of record for a study with at least 6 months advance written notice to the Principal Investigator (PI) and the Relying Organizations, in order to provide time for the protocol to be transferred to another IRB.

10) RIGHTS, DUTIES, AND RESPONSIBILITIES OF THE RELYING ORGANIZATION:

a) The Relying Organization will establish and follow its written policies and procedures as required, to comply with federal and state laws pertaining to the protection of human participants in research.
b) The Relying Organization bears responsibility for the conduct of all human subject research in which it is engaged.
c) The Relying Organization grants the reviewing IRB the authority to:
    i. Approve, require modifications to secure approval, and disapprove the research. The Relying Organization shall not approve specifically related

research that has not been approved by the Reviewing IRB.

ii. Suspend or terminate approval of the research when not being conducted in accordance with the Reviewing IRB's requirements or that has been associated with unexpected serious harm to subjects.

iii. Observe, or have a third party observe, the consent process and the conduct of the research.

d) The Relying Organization will ensure that each initial submission to the Reviewing IRB complies with any applicable local policies and procedures of the Relying Organization, prior to site activation.

e) The Relying Organization will comply with the prompt notification requirements of the Reviewing IRB.

f) The Relying Organization will collaborate with the Reviewing IRB on the investigation, management, and reporting to regulatory agencies and appropriate institutional officials of serious or continuing non-compliance, unanticipated problems involving risks to subjects or others, and suspensions and terminations of IRB approval.

g) The Relying Organization will modify its FWA to designate the IRB(s) of the other Participating Organizations.

h) The Relying Organization will accept or decline, on a case by case basis, in its sole discretion, to rely on the Reviewing IRB. The Relying Organization shall notify the Reviewing IRB of its decision, and will be unable to participate in the research presented by CTNeT.

i) The Relying Organization's IO may suspend or terminate the conduct of research at its local organization. If this occurs, the Relying Organization shall promptly notify the Reviewing IRB in writing.

11) CRITERIA FOR DETERMINING THE REVIEWING IRB

The reviewing IRB shall be used whenever research is sponsored or supported in whole or in part by CTNeT and involves the Research Sites.

12) MODIFICATIONS

No amendment to this MOU shall be valid unless it is reduced to writing and signed by authorized representatives of all parties.

13) CONFIDENTIALITY

Each party shall hold in confidence any information obtained from the other party within the scope of this MOU. The recipient party's obligation shall not apply to

information that:

a) is already in the recipient party's possession at the time of disclosure;
b) is or later becomes part of the public domain through no fault of the recipient party;
c) is received from a third party with no obligation of confidentiality to the disclosing party;
d) is independently developed by the recipient party;
e) is ethically required to be disclosed to participants because of any unforeseen risk identified by either party during or after completion of the study; or
f) is required by law or regulation to be disclosed.

In the event that information is required to be disclosed pursuant to subsection (f), the party required to make disclosure shall notify the other to allow that party to assert whatever exclusions or exemptions may be available to it under such law or regulation.

14) INDEPENDENT CONTRACTOR

It is mutually understood and agreed that in the performance of this MOU, the parties are at all times acting as independent contractors. None of the parties nor any of its employees shall for any purpose be deemed to be employees, agents, ostensible or apparent agents, servants, partners, or joint venturers of the other party.

15) ASSIGNMENT

None of the parties shall voluntarily or by operation of law, assign or otherwise transfer its rights or obligations under the terms of this MOU to any other entity without the prior written consent of the other party. Any attempted assignment or transfer by either party of its rights or obligations without such consent shall be void.

16) TERM AND TERMINATION

The term of this MOU is five years, beginning on the date of the last signature of the initial Participating Institution. If the termination date is on a weekend or designated holiday, then the MOU shall terminate on the next business day.

This MOU will not automatically renew, but the parties may agree in writing to renew it for additional three-year periods. Each Relying Organization will provide

written notice to the CTNeT of its intent to renew this MOU at least 60 days before the scheduled termination date.

Any party may terminate its participation in this MOU, with or without cause, by giving the other parties at least 60 days advances written notice of its intention to terminate. Termination shall be without penalty.

17) INDEMNIFICATION/HOLD HARMLESS

Each party, to the extent permitted by law, shall indemnify and hold the other party harmless from any and all liability, losses, damages, claims, or expenses of any kind, that result from the party's willful misconduct or negligent acts or omissions.

18) NOTICES

Any party giving or making any notice, request, demand, or other communication (each, a "notice") pursuant to this MOU must give the notice in writing by one of the following means: personal delivery; registered or certified mail (in each case, return receipt requested); nationally recognized overnight courier; electronic mail; or facsimile. Any party giving notice must address the notice to the appropriate person at the receiving party at the address listed below:

University of Texas at Arlington (UTA) – IORG0001464
Federalwide Assurance #: FWA00001762
IRB Registration #: IRB00005768

University of Texas at Austin (UTAustin) – IORG0000091
Federalwide Assurance #: FWA00002030
IRB Registration #: IRB00000130

University of Texas Brownsville - IORG0002687
Federalwide Assurance #: FWA00004472
IRB Registration #: IRB00003261

University of Texas at Dallas (UTD) – IORG0000054
Federalwide Assurance #: FWA00005412
IRB Registration #: IRB00000076

University of Texas at El Paso (UTEP) – IORG0000191
Federalwide Assurance #: FWA00001224

IRB Registration #: 00000311

University of Texas Pan American – IORG0001139
Federalwide Assurance #: FWA00000805
IRB Registration #: IRB00001540

University of Texas Pan American – IORG0005915
Federalwide Assurance #: FWA00014669
IRB Registration #: IRB00007130

University of Texas San Antonio (UTSA) – IORG0002490
Federalwide Assurance #: FWA00003861
IRB Registration #: IRB00003048

University of Texas Tyler – IORG0004460
Federalwide Assurance #: FWA00009775
IRB Registration #: IRB00005292

University of Texas Southwestern (UT Southwestern) – IORG0000638
Federalwide Assurance #: FWA00005087
IRB Registration #: IRB00000974, IRB00000975, IRB00000976, IRB00003142

University of Texas Medical Branch (UTMB) – IORG0000137
Federalwide Assurance #: FWA00002729
IRB Registration #: IRB00000757, IRB00000232

University of Texas Health Science Center at Houston (UTHEALTH) – IORG0000188
Federalwide Assurance #: FWA00000667
IRB Registration #: IRB00000308, IRB00003763, IRB00004604

University of Texas Health Science Center at San Antonio (UTHSCSA) - IORG0000312
Federalwide Assurance #: FWA00005928
IRB Registration #: IRB00000553, IRB00002691, IRB00002692

University of Texas Health Science Center Tyler – IORG0000370
Federalwide Assurance #: FWA000000003494
IRB Registration #: IRB00000627, IRB00002921

University of Texas M.D. Anderson Cancer Center – IORG0000083
Federalwide Assurance #: FWA00000363
IRB Registration #: IRB00000121, IRB00002203, IRB00003869, IRB00005015, IRB00006023

The undersigned have read and agreed to all of the terms above, and have the authority to bind their respective organizations. Written concurrence AND the designation of the applicable IRBs on each organization's FWA is required for this MOU to have legal effect, as memorialized by signature below.

Signature of Signatory Official (CTNeT):
Statewide Clinical Trials Network of Texas

_____ Date: _____
Name: Patty Winger
Chief Operating Officer, CTNeT

NOTE: The IRB of CTNeT must be designated on the OHRP-approved FWA for Research Site.

Signature of Signatory Official (Research Site):
_____

Print Full Name*:* _____
Institutional Title*:* _____ Date: _____

_____
Name:_____ Date: _____
IRB Chairperson
[Research Site] IRB

Appendix 1.1

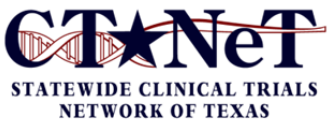
The University of Texas [Institution] has IRB Agreements with several affiliate institutions. These affiliates will not sign this MOU, but may participate in this Reliance Agreement. The affiliate institutions will designate the IRBs of institutions participating in this Reliance Agreement on their FWAs.

Institutions that rely on The University of Texas [Institution] which is a party to this MOU and have agreed to participate in this Reliance Agreement:

1) <Institution>
   Federalwide Assurance (FWA) #: FWA

EXHIBIT C

WORK ORDER TEMPLATE



CTNeT Study No.: _____
Clinical Research Study Title: _____
_____
_____
Study Chair: _____

SAMPLE WORK ORDER

This Work Order is agreed to in accordance with the Network Clinical Trial Agreement (the **"Agreement"**) between Statewide Clinical Trials Network of Texas (**"CTNeT"**) and _____ (**"Research Site")** and incorporates all the terms, definitions, and conditions explained in the Agreement. Any terms not otherwise defined in this Work Order shall have the same meaning ascribed to them in the Agreement.

1. Study Schedule

Projected Open to Accrual Date: _____

Projected Enrollment Period: _____

Projected Total Study Accrual: _____

2. Payment Terms

2.1 Payments shall consist of direct and indirect costs as outlined in the attached Study Budget (the **"Budget"**). The Budget will indicate Study payment milestones, such as patient accrual and completed "Case Report Forms" (**"CRFs"**).

2.2 CTNeT will disburse payment to the Research Site on a quarterly basis for work performed on the Study. Study-specific invoices, if any and as outlined in the Budget, are paid as received on a monthly basis.

2.3 Payment is contingent upon prompt completion and, if necessary, correction of the CRFs. For purposes of this Agreement, CRFs are considered "complete" when sent electronically and in a reasonably "monitor ready" format.

2.4 In no event shall CTNeT be obligated to pay any sums for additional services performed without CTNeT's prior written approval or services not included on the Budget, except as otherwise noted.

2.5 Payments to Research Site shall be sent to:

_____
_____
_____
Attention: Accounts Receivable

Tax Identification Number: _____

Note: Please verify accuracy of the above information and make corrections if needed.

3. Study-related Data Obligations

3.1 A completed CRF shall mean a case report that is either (a) monitor-ready at Research Site's location or (b) submitted electronically for a human subject who properly qualified, participated in, and completed the Study in accordance with Study requirements.

3.2 The Principal Investigator or designee will complete CRFs in a timely manner throughout the performance of the Study. Principal Investigator or designee will ensure CRFs are monitor ready within two (2) weeks after a Study subject visit.

3.3 Research Site shall maintain CRFs and source documentation.

3.4 Research Site will respond to any data queries within two weeks or to critical queries for data base lock within 72 hours.

4. Study Termination and Work Order Amendments

4.1 The Study may be terminated upon written notice if any of the following conditions occurs:

a. Automatically, effective as promptly as medically possible upon receipt of notice to terminate, if the authorization and approval for the Research Site to conduct a Study in its entirety is withdrawn by the FDA, the CIRB, or other regulatory authority;

b. By either Party, effective immediately, if any adverse event or side effect with the Study Agent or any other product(s) administered in the Study has occurred or the occurrence thereof is of such magnitude or likelihood that, in the reasonable and good faith opinion of Study Chair, CTNeT and/or Research Site, will support termination; or

c. Automatically, effective as promptly as medically possible upon receipt of notice to terminate, if CTNeT elects to discontinue conducting the Study.

4.2 The effect of such termination shall be governed by Section 8.3 of the Agreement.

4.3 Any modification, amendment, or supplement to this Work Order and/or

related attachments shall be in writing and signed by an authorized representative of each Party.

By signing this Work Order, Research Site represents and certifies that it has the authority to bind all clinic sites (locations) listed below in connection with this Work Order. In the event of a conflict between this Work Order and the Agreement, the terms of this Work Order shall control unless specifically noted to the contrary in either document. This Work Order is entered into and made effective as of the last date signed.

Accepted and Agreed to by:

Research Site:
_____

By: _____
Print Name: _____
Title: _____

Statewide Clinical Trials Network of Texas

By: _____
Name: Patricia A. Winger
Title: Vice President and Chief Operating Officer

Principal Investigator's Assurance:

I acknowledge that I have read this Work Order and the Agreement referred to herein and I agree to and will comply with all the terms and conditions of each, whether such obligations are imposed upon the Investigator or the Research Site or both.

By: _____
Print Name: _____
Principal Investigator for Research Site

List of attachments:
Attachment 1: Protocol
Attachment 2: Study Budget

EXHIBIT D

RESEARCH SITE NOTICE CONTACTS

The University of Texas at Austin Bill Catlett Director Office of Industry Engagement P.O. Box 7727 Austin, Texas 78713-7727 Overnight address: 101 E. 27th Street North Office Bldg. A (NOA), Suite 5.200 Austin, Texas 78712 Phone: 512-471-3866 Fax: 512-471-7839 Tax ID: 74-6000203	**The University of Texas at El Paso** Lee Ann Koehler Director Office of Legal Affairs 500 W. University Avenue El Paso, TX 79968-0587 Phone: 915-747-5056 Facsimile: 915-747-8701 Tax ID: 74-6000813
The University of Texas Health Science Center at Houston Jodi Ogden Executive Director, Sponsored Projects Administration 7000 Fannin Street, Suite 1006 Houston, TX 77030 Phone: 713-500-33999 Fax: 713-383-3746 Tax ID: 74-1761309	**The University of Texas Health Science Center at San Antonio** Jane A. Youngers Assistant Vice President for Research and Sponsored Programs 7703 Floyd Curl Dr, Mail Code 7828 San Antonio, TX 78229-3900 Phone: 210-567-2340 Fax: 210-567-2344 Tax ID: 74-1586031
The University of Texas Health Science Center at Tyler Conna Sutton Director, Office of Pre-Award Services 11937 U.S. Hwy. 271 Tyler, TX 75708-3154 Phone: 903-877-7585 Fax: 903-877-7558 Tax ID: 75-6001354	**The University of Texas Medical Branch at Galveston** Susan Ramsey Manager of Research Operations Office of Sponsored Projects 301 University Boulevard 4.40 Rebecca Sealy Hospital Galveston, TX 77555-0156 Phone: 409-266-9413 Fax: 409-266-9469 Tax ID: 74-6000949

The University of Texas **M. D. Anderson Cancer Center** Legal Services 1020 Holcombe Boulevard Suite 1550 Houston, TX 77030 Phone: 713-745-6633 Facsimile: 713-745-6029 And **The University of Texas** **M. D. Anderson Cancer Center** Houston Mitchell Director, Research Agreements 1515 Holcombe Boulevard, Unit 537 Legal Services Department Houston, TX 77030 Phone: 713-563-3881 Facsimile: 713-792-6878 Tax ID: 74-6001118	**The University of Texas Southwestern Medical Center** Angela R. Charboneau Wishon, J.D. Vice President for Research Administration 5323 Harry Hines Blvd. Dallas, Texas 75390-9105 Phone: 214-648-4494 Fax: 214-648-4474 Tax ID: 75-6002868