

Proposed
Standardized/Harmonized
Clauses for Clinical Trial
Agreements

Discussion Draft
August 27, 2008



INTRODUCTION

The Proposed Standardized/Harmonized Clauses for Clinical Trial Agreements are provided for informational purposes only. The CEO Roundtable, the National Cancer Institute and those who have assisted with the preparation of the clauses make no representations or warranties, express or implied, with respect to the clauses. The clauses are not offered as legal advice and should not be used as a substitute for seeking professional legal advice. The CEO Roundtable, the National Cancer Institute and those who have assisted with the preparation of the clauses are not responsible for any results of the use of these clauses.

The Proposed Standardized/Harmonized Clauses for Clinical Trial Agreements are presented in two groups:

Part I: Clauses for company-sponsored Clinical Trial Agreements

Part II: Clauses for investigator-initiated Clinical Trial Agreements

DRAFTING NOTE

Although the proposed clauses include references to Company, Research Institution and Principal Investigator, a company and a research institution may agree that a principal investigator who is employed by the research institution need not be a party to a Clinical Trial Agreement. In this circumstance, they may agree that the Principal Investigator need not be identified as a party in the heading of the agreement and that the words “Acknowledged by”, “I acknowledge that I have read the Agreement” or “I acknowledge that I have read, understood and accepted the Agreement” may be inserted above a signature line for the Principal Investigator on the signature page.

COMMON DEFINITIONS

All of the proposed clauses use the following defined terms:

“Protocol” means the clinical protocol entitled “_____” as it may be modified from time to time by mutual agreement of Company and Research Institution and approval of the institutional review board and applicable regulatory authorities.

“Study” means the clinical trial that is to be performed in accordance with this Agreement and the Protocol for purposes of gathering information about the compound/medical device identified in the Protocol.

PART I:

PROPOSED
STANDARDIZED/HARMONIZED CLAUSES FOR
COMPANY-SPONSORED CLINICAL TRIAL AGREEMENTS

INTELLECTUAL PROPERTY

(a) Pre-existing Intellectual Property. Ownership of inventions, discoveries, works of authorship and other developments existing as of the Effective Date hereof, and all patents, copyrights, trade secret rights and other intellectual property rights therein (collectively, "Pre-existing Intellectual Property"), is not affected by this Agreement, and neither party shall have any claims to or rights in any Pre-existing Intellectual Property of the other party, except as may be otherwise expressly provided in any other written agreement between the parties.

(b) Inventions. For purposes hereof, the term "Inventions" means all inventions, discoveries and developments conceived, first reduced to practice or otherwise discovered or developed by either party or any of such party's personnel in performance of the Study. In the first instance, (i) Company shall own all Inventions, that are conceived, first reduced to practice or otherwise discovered or developed solely by Company or any of its personnel; (ii) Research Institution shall own all Inventions that are conceived, first reduced to practice or otherwise discovered or developed by Research Institution or any of its personnel, and (iii) the parties who contribute to conception, reduction to practice, or other discovery or development of any Inventions shall own such Inventions jointly.

(c) Assignment. Research Institution shall, and shall cause its personnel to, disclose all Inventions promptly and fully to Company in writing, and Research Institution, on behalf of itself and its personnel, hereby assigns to Company all of its rights, title and interest in and to Inventions, including all patents, copyrights and other intellectual property rights therein and all rights of action and claims for damages and benefits arising due to past and present infringement of said rights. Research Institution shall cooperate and assist Company by executing, and causing its personnel to execute, all documents reasonably necessary for Company to secure and maintain Company's ownership rights in Inventions.

(d) License. Company hereby grants to Research Institution a perpetual, non-exclusive, non-transferable, paid-up license, without right to sublicense, to use Inventions, subject to the obligations set forth in Section (Confidentiality), for internal, non-commercial research and for educational purposes.

(e) Patent Prosecution. Research Institution and Principal Investigator shall cooperate, at Company's request and expense, with Company's preparation, filing, prosecution, and maintenance of all patent applications and patents for Inventions.

(f) Survival. This Section shall survive termination or expiration of this Agreement.

SUBJECT INJURY

Company shall reimburse Research Institution for the direct, reasonable and necessary medical expenses incurred by Research Institution for the treatment of any adverse event experienced by, illness of or bodily injury to a Study subject that is caused by treatment of the Study subject in accordance with the Protocol, except to the extent that such adverse event, illness or personal injury is caused by (a) failure by Research Institution, Principal Investigator or any of their respective personnel to comply with this Agreement, the Protocol, any written instructions of Company concerning the Study, or any applicable law, regulation or guidance, including good clinical practices, issued by any regulatory authority, or (b) negligence or willful misconduct by Research Institution, Principal Investigator or any of their respective personnel. This Section shall survive termination or expiration of this Agreement.

INDEMNIFICATION

(a) By Company. Company shall indemnify, defend, and hold harmless Research Institution and its trustees, directors and personnel, including Principal Investigator (collectively, the “Indemnitees”) from and against any and all liabilities, damages, losses, claims, and expenses, including court costs and reasonable attorneys’ fees (“Losses”) resulting from or arising out of any third-party claims, actions or proceedings arising out of (i) personal injury to or death of any Study subject enrolled in the Study, which injury or death is caused by treatment of such Study subject in accordance with the Protocol, or (ii) Company’s use or publication of Study Data, in each case solely to the extent that such Losses do not arise out of or in connection with any Research Institution Indemnitee’s (A) failure to comply with this Agreement, the Protocol, any written instructions of Company concerning the Study, or any applicable law, regulation or guidance, including good clinical practices, issued by any regulatory authority or (B) negligence or willful misconduct.

(b) Conditions of Indemnity. An Indemnitee claiming a right of indemnification or defense under this Agreement shall provide Company prompt written notice (in all events within thirty (30) days) of any such claim, including a copy thereof, served upon it, and shall cooperate fully with Company and its legal representatives in the investigation of any matter regarding the subject of indemnification, at Company’s expense; provided, however, that failure by an Indemnitee to provide prompt notice shall not relieve Company of its obligations hereunder except to the extent that Company is prejudiced by such failure. Company shall have the right to exercise sole control over the defense and settlement of any such complaint or claims for which indemnification or defense is sought, including the sole right to select defense counsel and to direct the defense or settlement of any such claim or suit; provided that Company shall not enter into any non-monetary settlement or admit fault or liability on behalf of any Indemnitee without the prior written consent of such Indemnitee, which consent shall not be unreasonably withheld or delayed. An Indemnitee shall have the right to select and to obtain representation by separate legal counsel at the Indemnitee’s sole expense.

(c) Survival. This Section shall survive termination or expiration of this Agreement.

DATA

(a) Definitions. For purposes of this Agreement, the term “Medical Records” means the medical records of Study subjects in connection with the Study, including, without limitation, treatment entries, x-rays, biopsy reports, ultrasound photographs and other diagnostic images; and the term “Study Data” means all records and reports, other than Medical Records, collected or created pursuant to or prepared in connection with the Study including, without limitation, reports (e.g., case report forms, any data summaries, any interim reports and the final report) required to be delivered to Company pursuant to the Protocol and all records regarding inventories and dispositions of all Study drugs/Study devices.

(b) Collection and Storage. Research Institution and Principal Investigator shall ensure the prompt, complete, and accurate collection, recording and classification of the Medical Records and Study Data. Research Institution and Principal Investigator shall (i) maintain and store Medical Records and Study Data in a secure manner with physical and electronic access restrictions, and environmental controls appropriate to the applicable data type and in accordance with applicable laws, regulations and industry standards; and (ii) protect the Medical Records and Study Data from unauthorized use, access, duplication, disclosure, loss and damage.

(c) Retention and Destruction. Research Institution shall maintain all Medical Records and Study Data for as long as required by applicable laws and regulations. Neither Research Institution nor Principal Investigator shall destroy or permit the destruction of any Medical Records or Study Data without prior written notification to the Company, and Research Institution shall continue to store Medical Records and Study Data, at the Company’s expense, for any period that the Company may request in writing after retention is no longer required by any applicable law or regulation.

(d) Ownership. Research Institution shall retain ownership of Medical Records, and Research Institution, on behalf of itself and its personnel, hereby assigns to Company all of its respective rights, title and interest, including intellectual property rights, in and to Study Data.

(e) Access and Use. Research Institution shall provide copies of all Study Data to Company for Company’s use. Research Institution and Principal Investigator shall afford Company and its representatives and their designees reasonable access to their respective facilities and to Medical Records so as to permit Company and its designees to monitor the Study. Research Institution and Principal Investigator shall, upon request, afford regulatory authorities reasonable access to their respective facilities and to Medical Records and Study Data, and the right to copy Medical Records and Study Data.

(f) License. Company hereby grants to Research Institution a perpetual,

non-exclusive, nontransferable, paid-up license, without right to sublicense, to use Study Data (i) subject to the obligations set forth in Section (Confidentiality), for internal, non-commercial research and for educational purposes, and (ii) for preparation of publications in accordance with Section (Publication Rights).

(g) Survival. This Section shall survive termination or expiration of this Agreement.

CONFIDENTIALITY

(a) Definition. "Confidential Information" means the confidential and proprietary information of Company and includes (i) all information disclosed by or on behalf of Company to Research Institution, Principal Investigator or other Research Institution personnel, including without limitation, the Study drug/Study device, technical information relating to the Study drug/Study device, all Pre-Existing Intellectual Property of Company, and the Protocol; and (ii) Study enrollment information, information pertaining to the status of the Study, communications to and from regulatory authorities, information relating to the regulatory status of the Study drug/Study device, and Study Data and Inventions. Confidential Information shall not include information that: (x) can be shown by documentation to have been public knowledge prior to or after disclosure by Company, other than through wrongful acts or omissions attributable to Research Institution or any of its personnel; (xi) can be shown by documentation to have been in the possession of Research Institution or any of its personnel prior to disclosure by Company, from sources other than Company that did not have an obligation of confidentiality to Company; (xii) can be shown by documentation to have been independently developed by Research Institution or any of its personnel; or (xiii) is permitted to be disclosed by written authorization from Company.

(b) Obligations. Research Institution and its personnel shall not (i) use Confidential Information for any purpose other than the performance of the Study or (ii) disclose Confidential Information to any third party, except as permitted by this Section ____, by Section ____ (Publication Rights), as required by law or by a regulatory authority or as authorized in writing by the disclosing party. To protect Confidential Information, Research Institution agrees to: (xi) limit dissemination of Confidential Information to only those personnel having a "need to know"; (xii) advise all personnel who receive Confidential Information of the confidential nature of such information; and (xiii) use reasonable measures to protect Confidential Information from disclosure. Nothing herein shall limit the right of Research Institution and Principal Investigator to disclose Study Data as permitted by Section ____ (Publication Rights).

(c) Compelled Disclosure. In the event that Research Institution or Principal Investigator receives notice from a third party seeking to compel disclosure of any Confidential Information, the notice recipient shall provide Company with prompt notice so that Company may seek a protective order or other appropriate remedy. In the event that such protective order or other remedy is not obtained, the notice recipient shall furnish only that portion of the Confidential Information which is legally required to be disclosed, and shall request confidential treatment for the Confidential Information.

(d) Return or Destruction. Upon termination of this Agreement or upon any earlier written request by Company at any time, Research Institution and

Principal Investigator shall return to Company, or destroy, at Company's option, all Confidential Information other than Study Data.

(e) Survival. This Section shall survive termination or expiration of this Agreement for five (5) Years.

PUBLICATION RIGHTS

(a) Publication and Disclosure. Research Institution and Principal Investigator shall have the right to publish or present the results of Research Institution's and Principal Investigator's activities conducted under this Agreement, including Study Data, only in accordance with the requirements of this Section. Research Institution and Principal Investigator agree to submit any proposed publication or presentation to Company for review at least thirty (30) days prior to submitting any such proposed publication to a publisher or proceeding with such proposed presentation. Within thirty (30) days of its receipt, Company shall advise Research Institution and/or Principal Investigator, as the case may be, in writing of any information contained therein which is Confidential Information (other than Study Data) or which may impair the availability of patent protection for Inventions. Company shall have the right to require Research Institution and/or Principal Investigator, as applicable, to remove specifically identified Confidential Information (other than Study Data) and/or to delay the proposed publication or presentation for an additional sixty (60) days to enable Company to seek patent protection for Inventions.

(b) Multi-Center Publications. If the Study is a multi-center study, Research Institution and Principal Investigator agree that they shall not, without the Company's prior written consent, independently publish, present or otherwise disclose any results of or information pertaining to Research Institution's and Principal Investigator's activities conducted under this Agreement until a multi-center publication is published; provided, however, that if a multi-center publication is not published within eighteen (18) months after completion of the Study and lock of the database at all research sites or any earlier termination or abandonment of the Study, Research Institution and Principal Investigator shall have the right to publish and present the results of Research Institution's and Principal Investigator's activities conducted under this Agreement, including Study Data, solely in accordance with the provisions of Section (a) above.

(c) Confidentiality of Unpublished Data. The parties acknowledge and agree that Study Data that is not published, presented or otherwise disclosed in accordance with Section (a) above ("Unpublished Data") remains within the definition of Confidential Information, and Research Institution and Principal Investigator shall not, and shall require their personnel not to, disclose Unpublished Data to any third party or disclose any Study Data to any third party in greater detail than the same may be disclosed in any publications, presentations or disclosures made in accordance with Section (a) above.

(d) Media Contacts. Research Institution shall not, and shall ensure that its personnel, including Principal Investigator do not, engage in interviews or other contacts with the media, including but not limited to newspapers, radio, television and the Internet, related to the Study, the Study drug/Study device, Inventions, or

Study Data without the prior written consent of Company. This provision does not prohibit publication or presentation of Study Data in accordance with Section (a) above.

(e) Registry and Reporting. Company will register the Study with a public clinical trials registry in accordance with applicable laws and regulations and will report the results of the Study publicly when and to the extent required by applicable laws and regulations.

(f) Survival. This Section shall survive termination or expiration of this Agreement.

MISCELLANEOUS

(a) Order of Precedence. In the event of any inconsistency between this Agreement and the Protocol, this Agreement shall govern and control as to any legal issue, and the Protocol shall govern and control as to any issue regarding treatment of Study subjects.

(b) Compliance with Laws. Research Institution, Principal Investigator and their personnel shall perform the Study at Research Institution's facility according to the Protocol and this Agreement, and shall comply with all:
(i) applicable local, state and federal laws and regulations relating to the conduct of the Study, and (ii) good clinical practices, including, without limitation, the requirements for obtaining prior written informed consent from each Study subject in accordance with the requirements of the Food and Drug Administration ("FDA"), any other regulatory authorities and the Institutional Review Board that is responsible for reviewing the Study ("IRB"), which shall include written authorization by the Study subject to use and disclose health information and Biological Samples for research in accordance with the health information privacy standards promulgated under the Health Insurance Portability and Accountability Act of 1996 and codified at 45 C.F.R. Parts 160 & 164, as may be amended from time to time (HIPAA).

(c) Company Review of Informed Consent Form. It is the intention of the parties that the informed consent form used by Research Institution with Study subjects shall be consistent in all respects with this Agreement, and Research Institution shall afford Company an opportunity to review the informed consent form before obtaining signed informed consent forms from any Study subjects. In the event that Company notifies Research Institution of any inconsistency between this Agreement and the informed consent form and Research Institution does not correct such inconsistency within a reasonable time after Company's notification, Company shall be entitled to terminate this Agreement without further obligation to Research Institution.

PART II:

**PROPOSED
STANDARDIZED/HARMONIZED CLAUSES FOR
INVESTIGATOR INITIATED CLINICAL TRIAL AGREEMENTS**

INTELLECTUAL PROPERTY AND LICENSING

(a) Pre-existing Intellectual Property. Ownership of inventions, discoveries, works of authorship and other developments existing as of the Effective Date hereof, and all patents, copyrights, trade secret rights and other intellectual property rights therein (collectively, "Pre-existing Intellectual Property"), is not affected by this Agreement, and neither party shall have any claims to or rights in any Pre-existing Intellectual Property of the other party, except as may be otherwise expressly provided in any other written agreement between the parties.

(b) Inventions. For purposes hereof, the term "Inventions" means all inventions, discoveries and developments conceived, first reduced to practice or otherwise discovered or developed by either party or any of such party's personnel in performance of the Study, and (i) Company shall own all Inventions, that are conceived, first reduced to practice or otherwise discovered or developed solely by Company or any of its personnel; (ii) Research Institution shall own all Inventions that are conceived, first reduced to practice or otherwise discovered or developed by Research Institution or any of its personnel, and (iii) the parties shall jointly own any Inventions that are first conceived, reduced to practice, or otherwise discovered or developed jointly by Research Institution and Company or any of their respective personnel.

(c) Disclosure. Promptly upon the conception, first reduction to practice, discovery or other development of any Invention that is owned by Research Institution, or that is jointly owned by Company and Research Institution, Research Institution shall submit to Company a reasonably detailed written disclosure of such Invention. Such disclosure shall include information Company reasonably needs in order to determine whether to exercise the option described in Section (e) below with respect to such Invention.

(d) License. Research Institution hereby grants to Company, in consideration for the rights and obligations set forth in this Agreement, and company hereby accepts, a non-exclusive, paid-up license to practice and exploit any Invention that is owned by Research Institution.

(e) Option. Research Institution hereby grants to Company a first option to negotiate an exclusive, worldwide, royalty-bearing license, with the right to grant sublicenses, to practice and exploit (i) any Invention that is owned by Research Institution or (ii) Institution's interest in any Invention that is jointly owned by Research Institution and Company. Company may exercise its option with regard to any such Invention at any time during a period of ninety (90) days after its receipt of disclosure of such Invention in accordance with Section (c) above by providing Research Institution written notice of Company's desire to exercise its option. Upon Company's exercise of an option in accordance herewith, Research Institution and Company will negotiate in good faith, for up to one hundred eighty

(180) days or any longer period on which the applicable parties may mutually agree, in order to reach agreement on a license agreement on commercially reasonable terms that is satisfactory to both parties. If Company has not exercised any option upon expiration of the applicable ninety (90) day option period, or if the parties have failed to reach agreement upon and execute a license agreement for the Invention that is the subject matter of an option exercised by Company in accordance herewith upon expiration of the one hundred eighty (180) day negotiation period, Research Institution shall have no further obligation to Company under this Agreement with regard to the applicable Invention.

(f) Retained Rights. If Research Institution grants Company an exclusive license to any Invention, Research Institution shall retain a perpetual, non-exclusive, non-transferable, paid-up license, without right to sublicense, to use such Invention for internal, non-commercial research and for educational purposes.

(g) Patent Prosecution. Company may require Research Institution to seek patent protection for any Invention, and Company shall reimburse Research Institution for all expenses incurred by Research Institution in connection with the preparation, filing, prosecution, and maintenance of all patent applications and patents for any Invention (including interferences and re-examinations) as to which Company executes a license agreement with Research Institution or otherwise requests Research Institution to seek patent protection.

(h) Survival. This Section shall survive termination or expiration of this Agreement.

SUBJECT INJURY

n/a

INDEMNIFICATION

(a) By Research Institution. Research Institution shall indemnify, defend, and hold harmless Company, its affiliated entities and their respective personnel (each, a “Company Indemnitee”) from and against any and all liabilities, damages, losses, claims, and expenses, including court costs and reasonable attorneys’ fees (“Losses”) resulting from or arising out of any third-party claims, actions or proceedings caused by negligence or willful misconduct, whether by act or omission, of Research Institution or any of its personnel.

(b) By Company. Company shall indemnify, defend, and hold harmless Research Institution and its trustees, directors and personnel, including Principal Investigator (collectively, the “Research Institution Indemnitees”) from and against any and all Losses resulting from or arising out of any third-party claims, actions or proceedings relating to Company’s (i) failure to manufacture the Study drug/Study device in accordance with applicable specifications, good manufacturing practices and/or the requirements of applicable laws and regulations or (ii) use or publication of Study Data, in each case solely to the extent that such Losses do not arise out of or in connection with any Research Institution Indemnitee’s negligence or willful misconduct.

(c) Conditions of Indemnity. The party claiming a right of indemnification or defense under this Agreement shall provide the indemnifying party prompt written notice (in all events within thirty (30) days) of any such claim, including a copy thereof, served upon it, and shall cooperate fully with the indemnifying party and its legal representatives in the investigation of any matter regarding the subject of indemnification, at the indemnifying party’s expense; provided, however, that failure to provide prompt notice shall not relieve an indemnifying party of its obligations hereunder except to the extent that the indemnifying party is prejudiced by such failure. The indemnifying party shall have the right to exercise sole control over the defense and settlement of any such complaint or claims for which indemnification or defense is sought, including the sole right to select defense counsel and to direct the defense or settlement of any such claim or suit; provided that the indemnifying party shall not enter into any non-monetary settlement or admit fault or liability on behalf of any indemnified party without the prior written consent of the indemnified party, which consent shall not be unreasonably withheld or delayed. The indemnified party shall have the right to select and to obtain representation by separate legal counsel at the indemnified party’s sole expense.

(d) Survival. This Section ___ shall survive termination or expiration of this Agreement.

DATA

(a) Definitions. For purposes of this Agreement, the term “Medical Records” means the medical records of Study subjects in connection with the Study, including, without limitation, treatment entries, x-rays, biopsy reports, ultrasound photographs and other diagnostic images; and the term “Study Data” means all records and reports, other than Medical Records, collected or created pursuant to or prepared in connection with the Study including, without limitation, reports (e.g., case report forms, any data summaries, any interim reports and the final report) and all information regarding inventories and dispositions of all Study drugs/Study devices.

b) Collection and Storage. Research Institution and Principal Investigator shall ensure the prompt, complete, and accurate collection, recording and classification of the Study Data and Medical Records. Research Institution and Principal Investigator shall (a) maintain and store Study Data and Medical Records in a secure manner with physical and electronic access restrictions, and environmental controls appropriate to the applicable data type and in accordance with applicable laws, regulations and industry standards; and (b) protect the Study Data and Medical Records from unauthorized use, access, duplication, disclosure, loss and damage.

(c) Retention and Destruction. Research Institution shall maintain all Study Data and Medical Records for as long as required by applicable laws and regulations. Neither Research Institution nor Principal Investigator shall destroy or permit the destruction of any Study Data or Medical Records without prior written notification to the Company, and Research Institution shall continue to store Study Data and Medical Records, at the Company’s expense, for any period that the Company may request in writing after retention is no longer required by any applicable law or regulation.

(d) Access and Use. Research Institution and Principal Investigator shall afford Company and its representatives and their designees reasonable access to their respective facilities and to Study Data and shall, at Company’s expense, provide copies of the Study Data to Company for Company’s use for any purpose. Research Institution and Principal Investigator shall, upon request, afford regulatory authorities reasonable access to its facilities and to Medical Records and Study Data, and the right to copy Medical Records and Study Data.

(e) Acknowledgment. Research Institution and Principal Investigator shall have the right to use Study Data for any purpose.

(f) Survival. This Section shall survive termination or expiration of this Agreement.

CONFIDENTIALITY

(a) Definition. "Confidential Information" means the confidential and proprietary information of Company and includes all information disclosed by or on behalf of Company to Research Institution, Principal Investigator or other Research Institution personnel, including without limitation, the Study drug/Study device, technical information relating to the Study drug/Study device and all Pre-Existing Intellectual Property of Company. Confidential Information shall not include information that: (i) can be shown by documentation to have been public knowledge prior to or after disclosure by Company, other than through wrongful acts or omissions attributable to Research Institution or its personnel; (ii) can be shown by documentation to have been in the possession of Research Institution or its personnel, prior to disclosure by Company, from sources other than Company that did not have an obligation of confidentiality to Company; (iii) can be shown by documentation to have been independently developed by Research Institution or its personnel; or (iv) is permitted to be disclosed by written authorization from Company.

(b) Obligations. Research Institution and its personnel shall not (i) use the Confidential Information for any purpose other than the performance of the Study or (ii) disclose the Confidential Information to any third party, except as permitted by this Section, by Section (Publication Rights), as required by law or by a regulatory authority or as authorized in writing by the disclosing party. To protect Confidential Information, Research Institution agrees to: (xi) limit dissemination of Confidential Information to only those personnel having a "need to know"; (xii) advise all personnel who receive Confidential Information of the confidential nature of such information; and (xiii) use reasonable measures to protect the Confidential Information from disclosure.

(c) Compelled Disclosure. In the event that Research Institution or Principal Investigator receives notice from a third party seeking to compel disclosure of any Confidential Information, the notice recipient shall provide Company with prompt notice so that Company may seek a protective order or other appropriate remedy. In the event that such protective order or other remedy is not obtained, the notice recipient shall furnish only that portion of the Confidential Information which is legally required to be disclosed and shall request confidential treatment for the Confidential Information.

(d) Return or Destruction. Upon termination of this Agreement or upon any earlier written request by Company at any time, Research Institution shall return to Company, or destroy, at Company's option, all Confidential Information other than Study Data.

(e) Survival. This Section shall survive termination or expiration of this Agreement for five (5) Years.

PUBLICATION RIGHTS

(a) Publication and Disclosure. Research Institution and Principal Investigator shall have the right to publish or present the results of Research Institution's and Principal Investigator's activities conducted under this Agreement only in accordance with the requirements of this Section. Research Institution and Principal Investigator agree to submit any proposed publication or presentation to Company for review at least thirty (30) days prior to submitting such proposed publication to a publisher or proceeding with such proposed presentation. Within thirty (30) days of its receipt, Company shall advise Research Institution and/or Principal Investigator, as the case may be, in writing of any information contained therein which is Confidential Information to Company or which may impair the availability of patent protection for Inventions. Company shall have the right to require Research Institution and/or Principal Investigator, as applicable, to remove specifically identified Confidential Information and/or to delay the proposed publication or presentation for an additional sixty (60) days to enable Research Institution to seek patent protection for Inventions at Company's expense.

(b) Registry and Reporting. Research Institution will register the Study with a public clinical trials registry in accordance with applicable laws and regulations and will report the results of the Study publicly when and to the extent required by applicable laws and regulations.

(c) Survival. This Section shall survive termination or expiration of this Agreement.

MISCELLANEOUS

(a) Order of Precedence. In the event of any inconsistency between this Agreement and the Protocol, this Agreement shall govern and control as to any legal issue, and the Protocol shall govern and control as to any issue regarding treatment of Study subjects.

(b) Compliance with Laws. Research Institution, Principal Investigator and their personnel shall perform the Study at Research Institution's facility according to the Protocol and this Agreement, and shall comply with all:
(i) applicable local, state and federal laws and regulations relating to the conduct of the Study, and (ii) good clinical practices, including, without limitation, the requirements for obtaining prior written informed consent from each Study subject in accordance with the requirements of the Food and Drug Administration ("FDA"), any other regulatory authorities and the Institutional Review Board that is responsible for reviewing the Study ("IRB"), which shall include written authorization by the Study subject to use and disclose health information and Biological Samples for research in accordance with the health information privacy standards promulgated under the Health Insurance Portability and Accountability Act of 1996 and codified at 45 C.F.R. Parts 160 & 164, as may be amended from time to time (HIPAA).