Clinical Trial Agreements - A Moderated Discussion
Health Care Compliance Association
Research Compliance Conference
June 3, 2015

EXAMPLES – FOR DISCUSSION

1. PERSONNEL EXAMPLES

Personnel Example 1

*Institution agrees to and shall cause its employees, contractors, agents, representatives, and sub-contractors (collectively, "**Personnel**"), to perform the Services in accordance with this Agreement. Institution understands and agrees that the Services are intended to support a regulatory submission to one or more regulatory authorities. Institution agrees to cooperate with Company with presentations, administrative hearings or court proceedings, litigation or other matters related to the Services.*

Personnel Example 2

"Personnel" shall mean Institution, Principal Investigator and its employees, contractors, and representatives performing the Services hereunder.

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2. PAYMENT/COMPENSATION EXAMPLES

Payment Example 1

Payment. In consideration for Institution's and Investigator's performance under this Agreement, Sponsor shall pay Institution for actual services rendered in accordance with this Agreement, as outlined in the payment schedule included in Attachment B attached hereto. Institution shall then pay Investigator for actual services rendered in accordance with the Investigator payment schedule attached to the applicable Joinder. Unless otherwise specifically agreed to in Exhibit B Sponsor shall pay all invoices within thirty (30) days of receipt.

Payment Example 2

Payments are fully inclusive for all services provided in connection with the Study, including, without limitation, all applicable indirect costs, overhead, taxes, fees and other assessments due Institution, Investigator and other persons providing any services or goods to the subjects or in connection with the Study, and any IRB fees, wind-down fees, and reimbursements to the Subjects, and shall remain firm for the duration of the Study." (CTA; Exhibit B, pp. 1-2)

3. **EXPENSES EXAMPLES**

Expenses Example 1

Reimbursement of Expenses. Out of pocket expenses authorized in advance by Sponsor shall be reimbursed to Investigator or Institution within thirty (30) days of receipt by Sponsor of an itemized invoice.

Expenses Example 2

Sponsor shall only be responsible for the fees, costs and expenses specifically stated in Exhibit 1 attached hereto.

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4. ***PENALTIES EXAMPLE***

Penalties. To the extent that Sponsor does not make any payments in accordance with the terms of this Agreement all outstanding balances will be assessed a penalty of five percent (5%) per month or the maximum allowable by applicable law.

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5. **FAIR MARKET VALUE EXAMPLE**

Fair Market Value. The parties agree that the compensation set forth herein represents the commercially reasonable, fair market value of the services, negotiated in an arm's-length transaction, and has not been determined in a manner which takes into account the volume or value of referrals or business, if any, that may otherwise be generated between Institution and/or its Affiliates and Sponsor and/or its Affiliates.

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6. **TRANSPARENCY EXAMPLES**

Transparency Reporting Example 1

Transparency Reporting. Institution agrees that it will comply with its obligations pursuant to the Patient Protection and Affordable Care Act of 2010, as amended ("PPACA") when applicable, including but not limited to Section 6002 thereof which added Section 1128G to the Social Security Act of 1935, as amended, and all applicable proposed and final rules and regulations promulgated thereunder and any Sponsor policies related thereto (collectively referred to herein as the "Sunshine Act"). The Sunshine Act requires Sponsor to track and report payments to other transfers of value made by Sponsor (or by Institution on Sponsor's behalf) to certain individuals "Covered Recipients" wherever those transfers of value occur.

Transparency Reporting example 2

Transparency Reporting. INSTITUTION agrees that it will reasonably cooperate with Sponsor so that Sponsor may comply with its obligations pursuant to the Patient Protection and Affordable Care Act of 2010, as amended ("PPACA") when applicable, including but not limited to Section 6002 thereof which added Section 1128G to the Social Security Act of 1935, as amended, and all applicable proposed and final rules and regulations promulgated thereunder and any Sponsor policies related thereto (collectively referred to herein as the "Sunshine Act"). The Sunshine Act requires Sponsor to track and report payments to other transfers of value made by Sponsor (or by INSTITUTION on Sponsor's behalf) to certain individuals "Covered Recipients" wherever those transfers of value occur.

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7. **CONFIDENTIALITY EXAMPLES**

Confidentiality Examples

During the Term, including any extensions thereof, and for a period of five (5) years after the expiration or termination of this Agreement, Institution, its employees, including, without limitation, Investigator and subinvestigators, agents, and other personnel (including, without limitation, subcontractors and affiliates) (collectively, "Receiving Party") shall not disclose to any third party (other than Sponsor's designated parties) or use Confidential Information for any purpose other than that indicated in this Agreement without Sponsor's prior written consent. Notwithstanding the foregoing, obligations of confidentiality and non-use with respect to any Confidential Information identified as a trade secret by Sponsor shall remain in place for so long as the applicable Confidential Information retains its status as a trade secret under applicable Law. "Confidential Information" shall include any information provided to Receiving Party by or on behalf of Sponsor including, without limitation, the Protocol, Study Materials, and all materials, data, results, and information concerning Sponsor or the Study or developed as a result of conducting the Study, except any portion thereof that:

i. *is known to the Receiving Party prior to receipt thereof under this Agreement, as evidenced by its written records;*
ii. *is disclosed to the Receiving Party after acceptance of this Agreement by a third party who has a right to make such disclosure in a nonconfidential manner; or*
iii. *is or becomes part of the public domain through no fault of the Receiving Party.*

Within forty-five (45) days following the completion or termination of the Study, Institution shall return or destroy all Confidential Information. Notwithstanding the foregoing, Institution may retain necessary copies of Confidential Information only for (i) archival purposes, and (ii) compliance with applicable regulations or laws (including, without limitation, Study document

retention requirements set forth in 21 C.F.R. 312 and the generally accepted standards of good clinical practice as defined in the 1996 ICH Harmonized Tripartite Guideline for Good Clinical Practice E6).

Nothing in this Agreement shall be construed to restrict Receiving Party from disclosing Confidential Information as required by law or court order or other governmental order or request, provided in each case Receiving Party shall provide Sponsor and INSTITUTION prompt written notice (and in any case at least five (5) business days' notice) in order to allow Sponsor to take whatever action it deems necessary to protect its Confidential Information. In the event that no protective order or other remedy is obtained, or Sponsor waives compliance with the terms of this Section 8, Receiving Party shall furnish only that portion of the Confidential Information which it is advised by counsel as being legally required. In addition, Receiving Party shall permit Sponsor to attempt to limit such disclosure by appropriate legal means.

Confidentiality Example 2

Confidential Information. "Confidential Information" means any and all information, data, and know-how, whether written or oral, technical or non-technical, including, without limitation, any financial, business, marketing, or operations information, formulas, manufacturing processes, basic scientific data, prior clinical data, Data (defined herein) or other information provided by or on behalf of a Party or its Affiliates (the "Disclosing Party") to the other Party pursuant to this Agreement (the "Receiving Party").

Confidentiality Obligations. Confidential Information shall remain the sole and exclusive property of the Disclosing Party. For a period of five (5) years after the receipt of Confidential Information hereunder, the Receiving Party agrees to hold such Confidential Information in confidence, to only use such Confidential Information for the purposes of this Agreement and to only disclose such Confidential Information to its employees, agents, Affiliates, contractors and representatives who are bound by an obligation of confidentiality.

Exceptions. Confidential Information shall not include information that:

- *i. at the time of disclosure, or thereafter, has become publicly available, except by breach of this Agreement;*
- *ii. was in the possession of the Receiving Party prior to disclosure hereunder as evidenced by competent records;*
- *iii. was developed by a Receiving Party independently from and without reference to Confidential Information received hereunder; or*
- *iv. a Receiving Party received from a third party without an obligation of confidentiality.*

Compliance with Applicable Law. Notwithstanding any other terms contained herein, a Receiving Party may disclose Confidential Information received hereunder to the extent required by applicable law provided that such Receiving Party provides notice to the Disclosing Party as soon as reasonably practicable under the circumstances and agrees to cooperate in Disclosing Party's efforts to obtain a protective order or other appropriate remedy. Any information disclosed pursuant to this paragraph shall otherwise remain Confidential Information.

Return of Confidential Information. Upon request of a Disclosing Party, a Receiving Party shall return to such Disclosing Party all Confidential Information received from that Disclosing Party pursuant to this Agreement.

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8. **PUBLICATION EXAMPLE**

Publication Example 1

Institution and Investigator may publish or present the results of the Trial generated by Institution and Investigator (the "Trial Results") either: (i) with the advance written consent of Sponsor; or (ii) 2 years after the completion of the Trial at all participating institutions (each, a "Publication"). Investigator will submit all proposed Publications along with the name of the intended scientific journal, forum or conference, to Sponsor prior to submission of the Publication (30 days prior for manuscripts and 15 days for abstracts and oral presentations). Institution and Investigator will delete references to Sponsor's Confidential Information in any paper or presentation and, at Sponsor's request, delay such Publication for up to 45 days in order to permit Sponsor to obtain appropriate intellectual property protection on any Confidential Information contained in the Publication.

Publication Example 2

1. INSTITUTION Publications Rights. INSTITUTION shall have the right to publish the results of a Study and any background information provided by Sponsor which is necessary to include in any publication of research results or necessary for other scholars to verify such results ("Publication(s)"). INSTITUTION will provide Sponsor with a copy of a proposed Publication at least sixty (60) days prior to submission for publication. Notwithstanding the foregoing, in the event that a Publication takes the form of an abstract or poster presentation, INSTITUTION will provide Sponsor with a copy of a proposed Publication at least ten (10) days prior to submission for publication. Sponsor shall have the right to delay a Publication for sixty (60) days in order to obtain patent protection of any Inventions. Notwithstanding any other terms contained herein, publication in accordance with this Section (Publication) shall not be deemed a breach of INSTITUTION's confidentiality obligations contained herein.

2. Multi-Center Publications. Notwithstanding the foregoing, if a particular Study is part of a multicenter study, INSTITUTION agrees that the first publication of the Study results shall be made in conjunction with the presentation of a joint, multicenter publication. However, if a multicenter publication is not submitted within six (6) months after completion, abandonment or termination of the applicable Study at all Study sites, or if Sponsor confirms that there will be no multicenter publication, INSTITUTION may publish the Study results otherwise in accordance with the terms of this Agreement.

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9. **INTELLECTUAL PROPERTY EXAMPLE**

Intellectual Property Example 1

Non-Use. Investigator agrees to only use the Study Drug for the performance of the Study in accordance with the terms of this Agreement.

Inventions.

(1) It is recognized and understood by the parties that the existing inventions and technologies of each respective party are their separate property, respectively, and are not affected by this Agreement and no party shall have any claims to or rights in such existing inventions and technologies of any other party.

(2) Any inventions, discoveries or improvements conceived or reduced to practice as a direct result of Investigator's performance pursuant to this Agreement will be disclosed promptly to Sponsor and shall be deemed the property of Sponsor. Sponsor shall have full power and authority to file and prosecute patent applications throughout the world thereon, and Investigator agrees to do all things reasonably necessary to assist Sponsor in obtaining and enforcing any patents thereon, all at Sponsor's expense.

Intellectual Property Example 2

All inventions, ideas, methods, works of authorship, know-how or discoveries that are made, conceived, or reduced to practice by Institution, Investigator or Trial Personnel: (i) as a result of or in connection with the conduct of the Trial; (ii) that incorporate or use Confidential Information; or (iii) that are directly related to the Compound, and in each case together with all intellectual property rights relating thereto (collectively, "Trial Inventions"), will be the sole and exclusive property of Sponsor or its designee. Institution and Investigator will promptly disclose all Trial Inventions to Sponsor in writing. Institution hereby assigns, and will cause Investigator and Trial Personnel to assign, all right, title and interest in all Trial Inventions to Sponsor or its designee. At Sponsor's request and expense, Institution shall take, and shall cause Investigator and Trial Personnel to take, all additional actions as Sponsor deems necessary to perfect the

interest of Sponsor or its designee in Trial Inventions or to obtain patents or otherwise protect the interest of Sponsor or its designee in Trial Inventions.

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10. **MONITORING VISITS AND REGULATORY AUDITS EXAMPLE**

Sponsor Monitoring. During the term of the Agreement and for sixty (60) days after the last Study subject has completed the Study ("Completion Date"), Sponsor or Sponsor's designee ("Designees") may, at mutually agreeable times and on a confidential basis, inspect Institution's and Investigator's records, facilities, equipment, or procedures related to their respective obligations hereunder. Sponsor and Designees agree that to the extent that they are in receipt of Protected Health Information as defined by the Health Insurance Portability and Accountability Act of 1996 ("PHI") they shall agree to maintain the confidentiality thereof in perpetuity. Sponsor agrees to conduct its study close out visit by the Completion Date.

Regulatory Authority Audits. If a governmental or regulatory authority ("Regulatory Authority") gives notice to Institution or Investigator of an inspection or any other regulatory action directly related to the Study, Institution or Investigator, as applicable, will notify Sponsor as soon as reasonably practicable under the circumstances provided that they are permitted to provide such notice pursuant to applicable law. If reasonably practicable under the circumstances, Institution and/or Investigator, as applicable, will notify Sponsor prior to complying with any demand or request by a Regulatory Authority where such demand or request is directly related to Study. Institution or Investigator, as applicable, shall provide to Sponsor a copy of correspondence with Regulatory Authorities directly related to Study.

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11. **STUDY RECORD RETENTION EXAMPLE**

Study Records and Retention Period. Investigator shall maintain one (1) copy of all Study data and records generated as a direct result of the performance of the Study ("Study Records") for the longer of (1) two (2) years after the last marketing authorization for the Study Drug has been approved or Sponsor has discontinued its research with respect to such Study Drug, or (2) such longer period as required by applicable regulatory requirements (the "Retention Period"). Following the Retention Period, as reasonably instructed by Sponsor and at Sponsor's reasonable expense, Investigator will either (x) forward their Study Records to Sponsor, (y) retain their Study Records or (z) destroy their Study Records, and send Sponsor proof of such destruction. Study Records shall be the property of the Sponsor. Notwithstanding the foregoing or any other terms contained herein, medical records shall be the property of the applicable Investigator or his or her institution.

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12. PUBLICITY EXAMPLES

Publicity Example1

Publicity. iNSTITUTION will use the name of Sponsor or the Sponsor's employees or any of their trademarks in any advertising, sales promotional material, or press release without Sponsor's prior written approval, except to the extent such disclosure is reasonably necessary for: (i) regulatory filings, including filings with the U.S. Securities and Exchange Commission or the FDA (or any equivalent oversight body in a country other than the United States); (ii) prosecuting or defending litigation; and (iii) complying with applicable laws, rules, and regulations.

Publicity Example2

No party to this Agreement may use the name of any other party or any of its Affiliates, employees, contractors or agents in connection with any press release, advertising, promotional literature, or any other publicity matters without the prior written approval of such party; provided, however, that Investigator and Institution may acknowledge in general terms the existence of this Agreement and receipt of financial support from Sponsor without Sponsor's prior approval.

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13. *TERM AND TERMINATION EXAMPLES*

Term and Termination Example 1

Term. Unless terminated earlier by written notice of one Party to the other in accordance with Section XX.X, this Agreement will expire upon the later of the date on which: (i) Sponsor has received all completed CRFs from Institution; (ii) Institution has resolved all data clarification queries, and submitted the closeout reports to the IRB and to Sponsor to Sponsor's satisfaction; (iii) all Trial Site closeout activities have been completed; and (iv) Sponsor has made all payments and reimbursements and collected all refunds due under this Agreement.

Term and Termination Example 2

This Agreement shall commence as of the Effective Date and shall expire on the later of (i) one year or (ii) the completion of the Study, unless terminated earlier as provided herein.

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14. INDEMNIFICATION EXAMPLES

Indemnification Example 1

Sponsor Indemnification. Sponsor hereby agrees to save, defend, indemnify and hold harmless Provider and its Affiliates performing Services, officers, directors, employees, consultants and agents ("Provider Indemnitees") from and against any and all losses, damages, liabilities, expenses and costs, including reasonable legal expense and attorneys' fees ("Losses"), to which any such Provider Indemnitee may become subject as a result of any claim, demand, action or other proceeding by any third party ("Claim") to the extent such Losses arise out of: (a) the breach by Sponsor of any representation, warranty, covenant or agreement made by it under this Agreement; (b) the gross negligence or willful misconduct of any Sponsor Indemnitee; or (c) the development, manufacture, use, handling, storage, sale, administration of a Sponsor Product in accordance with the applicable Protocol, any non-standard of care procedures performed in accordance with a Protocol, or other disposition of any Sponsor Product by or on behalf of Sponsor; except, in each case, to the extent such Losses result from the material breach by Provider of any representation, warranty, covenant or agreement made by it under this Agreement or the negligence or willful misconduct of any Provider Indemnitee.

Indemnification Example 2

Reciprocal Indemnity. Either party ("Indemnifying Party") agrees to indemnify, hold harmmless and defend the other party, its Affiliates and their respective directors, officers, employees, contractors and agents (the "Indemnitee(s)") from and against any and all costs, expenses, liabilities, damages, losses and harm (including reasonable legal expenses and attorneys' and other professional fees incurred as a result of any defense hereunder) arising out of or resulting from any suits, claims, actions, allegations or demands brought by a third party against any Indemnitee (collectively, "Claims") caused by the Indemnifying Party's (including its Affiliates): (1) negligence, recklessness, willful malfeasance or lack of adherence to applicable laws; or (2) breach of this Agreement. No Party's obligations pursuant to the foregoing shall apply to the extent the applicable Claim was caused by the negligence, recklessness, willful malfeasance, lack of adherence to applicable law, or breach of this Agreement by an Indemnitee.

Sponsor Indemnity. In addition to the preceding, Sponsor shall indemnify CRO, Institution, the Investigator, and their respective Affiliates, directors, officers, employees, contractors and agents ("Indemnitee(s)") for any Claims caused by (1) Sponsor's (including its Affiliates) use of Inventions or Study data; (2) the Study Drug; and (3) any procedures required by the Protocol. Sponsor's obligations pursuant to this paragraph shall not apply to the extent the applicable Claim was caused by the negligence, recklessness, willful misconduct, lack of adherence to applicable law, or breach of this Agreement by an Indemnitee.

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15. SUBJECT INJURY EXAMPLES

Subject Injury Example 1

Subject Injury. If applicable to the Services, Provider, through its Phase I Units agrees to provide or arrange for prompt diagnosis and medical treatment of any medical injury experienced by a Study subject as a direct result of the Study subject's participation in a Sponsor-approved Protocol hereunder (a "Study"). To the extent that such costs are not reimbursed by the Study subject's medical insurance Sponsor will reimburse Provider for those reasonable and necessary medical expenses incurred by Study subjects for acute medical care provided or facilitated by Provider to treat any Study subject injuries directly caused by a Sponsor Product and/or non-standard of care procedures performed on Study subjects, which causality is determined by Provider, provided that the Sponsor Product and such non-standard of care procedures were administered in accordance with the Protocol and this Agreement, provided however, that Sponsor shall not pay Institution for any medical expenses to the extent that such Study subject injuries, directly or indirectly, arose out of or are related to any (i) Provider Indemnitee's (A) failure to follow any Applicable Laws, regulations, or guidelines, or to conform to reasonable and prudent clinical practices; (B) wrongful or negligent acts or omissions, or willful misconduct or misuse of the Study Drug; or (C) failure to comply with this Agreement, the Protocol or other written recommendations or instructions provided by or on behalf of Sponsor; (D) failure to obtain informed consent from the Study subject using the then current Informed Consent Form in the form approved by Sponsor; or (ii) any Study subject's failure to follow the instructions provided within the Protocol and listed in the Informed Consent Form. As used in this Section, the phrase "Study subject injuries" does not include the natural progression of an underlying or pre-existing condition or events that would have been expected from the standard treatment using currently approved therapies for the Study subject's condition, with the exception of aggravation of Study subject condition which is a requirement of participation. Any payments made under this section do not constitute an admission of liability for any injury, which ultimately could be determined only through an adjudication process, or as a settlement or compromise of any potential future liability claim.

Subject Injury Example 2

Sponsor shall be responsible for all necessary and reasonable costs associated with the diagnosis and treatment of injuries to any Study subjects caused by the Study Drug or procedures performed in accordance with the Protocol. Sponsor shall not be responsible for any costs pursuant to this paragraph to the extent that such injuries were caused the negligence, recklessness, willful malfeasance, lack of adherence to applicable laws, or breach of this Agreement by an Institution Indemnitee.

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16. MMSEA EXAMPLES

MMSEA Example 1

In order for Sponsor to meet its MMSEA obligations Institution agrees to provide to Sponsor or its designee the following information for each Study subject: 1.) First Name, 2.) Last Name, 3.) Date of Birth, 4.) Gender and 5.) Social Security Number (SSN).

MMSEA Example 2

Institution agrees that for each Study subject where Sponsor is responsible for Subject Injury Costs (as defined herein) Institution shall request from the Study subject the Study subject's name, date of birth, gender and social security number ("MMSEA Information") to be provided to Sponsor or its designee. Institution shall provide MMSEA to Sponsor or its designee upon receipt. Sponsor shall not use the MMSEA info except to fulfill its MMSEA obligations or otherwise in accordance with the Study subject's informed consent form or HIPAA Authorization.

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17. LIMITATION OF LIABILITY EXAMPLE

Limitation of Liability. EXCEPT FOR BREACH OF ARTICLE 6, IN NO EVENT SHALL EITHER PARTY NOR THEIR AFFILIATES BE LIABLE TO THE OTHER FOR ANY LOST PROFITS, LOST SAVINGS, OR ANY OTHER INCIDENTAL, SPECIAL, EXEMPLARY, OR CONSEQUENTIAL DAMAGES, EVEN IF SUCH PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES, ARISING OUT OF OR IN CONNECTION WITH THIS AGREEMENT.

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