MASTER CLINICAL TRIAL AGREEMENT

This Master Clinical Trial Agreement ("**AGREEMENT**") is made and entered into as of 13 August 2013 (the "**EFFECTIVE DATE**"),

BETWEEN:

UCB BIOSCIENCES INC., a corporation incorporated under the laws of the state of Delaware having its principal place of business at 8010 Arco Corporate Drive, Suite 100, Raleigh, North Carolina 27617 USA; hereinafter referred to as the "**SPONSOR**"

AND the member institutions of THE UNIVERSITY OF TEXAS SYSTEM, ("SYSTEM") having a place of business at 601 Colorado Street, Austin, TX 78701, as governed by its Board of Regents ("Board"): THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT TYLER, THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT HOUSTON, THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT SAN ANTONIO, THE UNIVERSITY OF TEXAS MEDICAL BRANCH AT GALVESTON, THE UNIVERSITY OF TEXAS AT AUSTIN, and THE UNIVERSITY OF TEXAS SOUTHWESTERN MEDICAL CENTER (hereinafter collectively or individually referred to as "INSTITUTION""), each with an office and place of business as set forth on Attachment 1 hereto.

SPONSOR and INSTITUTION, individually a "PARTY" and collectively the "PARTIES".

WHEREAS, the SPONSOR and its AFFILIATES (as defined below) are engaged in research and development of pharmaceutical products and/or medical devices and have developed or acquired proprietary know-how and technical information relating to such products or devices;

WHEREAS, the INSTITUTION has the expertise, capabilities and resources for conducting clinical trials; and

WHEREAS, the SPONSOR wishes to appoint the INSTITUTION from time to time to arrange and administer a STUDY or STUDIES (as defined below) to evaluate one or more of SPONSOR'S pharmaceutical products and/or medical devices by executing individual WORK ORDERs (as defined below) in relation to certain STUDIES and the INSTITUTION agrees to conduct such STUDIES in accordance with the terms and conditions set out in this AGREEMENT;

NOW, THEREFORE, the PARTIES, intending to be legally bound, have entered into this AGREEMENT and do specifically agree as follows:

DEFINITIONS AND INTERPRETATION

As used in this AGREEMENT, the following terms shall have the meanings set forth below (the singular including the plural and vice versa):

AFFILIATE shall mean with respect to a PARTY (i) any company at least fifty percent (50%) of whose issued and voting capital is owned or controlled, directly or indirectly, by said PARTY, or (ii) any company which owns or controls, directly or indirectly, at least fifty percent (50%) of the issued and voting capital of said PARTY, or (iii) any company owned or controlled, directly or indirectly, to the extent of at least fifty percent (50%) of the issued and voting capital, by any of the foregoing.

AUDIT shall mean any audit as defined in the GCP GUIDELINES (as defined below).

BACKGROUND INTELLECTUAL PROPERTY means INTELLECTUAL PROPERTY (as defined below) existing at the EFFECTIVE DATE of this AGREEMENT or developed independently of the activities under this AGREEMENT under the control of either PARTY and that is reasonably necessary, relevant or otherwise useful for performing the activities under this AGREEMENT. For the purposes of this definition "control" means ownership and/or the unrestricted right to grant access or licenses to third parties.

CLINICAL STUDY REPORT shall mean SPONSOR'S clinical study report form that conforms with the guidelines on structure and content of such forms set out in the GCP GUIDELINES.

CONFIDENTIAL INFORMATION shall mean any INFORMATION (as defined below) and/or MATERIALS (as defined below) disclosed by whatever means by a PARTY, or its AFFILIATES to the other PARTY or its AFFILIATES including but not limited to STUDY RESULTS (as defined below) and STUDY IP (as defined below), which is marked confidential or identified as confidential at the time of disclosure and, if disclosed orally, is reduced to writing within fifteen (15) business days of such verbal disclosure, or information that a reasonable person would consider to be confidential or proprietary information given the content and the circumstances of the disclosure.

CRO shall mean the Clinical Research Organization assigned by SPONSOR for a STUDY as specified in the respective WORK ORDER (as defined below) and which acts as an independent contractor, but not as a party to this AGREEMENT or any WORK ORDER

hereunder, to carry out on behalf of SPONSOR certain aspects of SPONSOR's responsibilities hereunder, which may include, but are not limited to, contract execution, payment, monitoring and/or other STUDY activities. To the extent that CRO negotiates on behalf of SPONSOR, SPONSOR shall require the CRO to use this AGREEMENT and its WORK ORDER template.

DEVICE shall mean an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease in man, or intended to affect the structure or any function of the body of man, or used in the delivery of a drug or compound through a specific route of administration and which does not achieve any of its primary intended purposes through chemical action within or on the body of man and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes as defined in the PROTOCOL (as defined below), supplied by SPONSOR for use in the STUDY.

ENROLLED SUBJECT shall mean an individual who: (i) meets the criteria for participation and continuing participation in the STUDY, as defined in the PROTOCOL; and (ii) signs an informed consent form approved by SPONSOR in accordance with this AGREEMENT after being duly informed of the nature, significance, implications and risks of the STUDY PRODUCT (as defined below) and the nature of the STUDY.

GCP GUIDELINES shall mean the current E6 Good Clinical Practice Guidelines: Consolidated Guidance relating to the implementation of good clinical practice ("GCP") in the conduct of clinical studies on medicinal products for human use,

INFORMATION means any inventions (whether patentable or not), data, instructions, ideas, software, algorithms, discoveries, procedures, methods, techniques, formulae, biological sequences, advice and any other knowledge each in whatever form, and case report forms ("CRFs"), the TRIAL MASTER FILE (as defined below), CLINICAL STUDY REPORT forms, all completed informed consent forms, subject diaries and adverse event reporting forms. For clarification INFORMATION does not include PATIENT MEDICAL RECORDS.

INTELLECTUAL PROPERTY means all PATENTS, trademarks, utility certificates and models, inventors' certificates, copyrights, database rights, designs, domain names, trade secrets, KNOW-HOW (as defined below) and any other proprietary rights, priority rights, prior user rights and all other rights of a like nature in each case whether registered or unregistered and in any jurisdiction.

INVESTIGATOR(S) shall mean the person responsible for the conduct of the STUDY at INSTITUTION, who is employed by the INSTITUTION and will be designated in the applicable WORK ORDER. The INVESTIGATOR will perform the STUDY in accordance with the terms and conditions set out in this AGREEMENT and the applicable WORK ORDER. If a STUDY is conducted by a team of individuals at INSTITUTION, the INVESTIGATOR is the responsible leader of the team and may be called the principal investigator.

IRB shall mean Institutional Review Board.

KNOW-HOW means INFORMATION and/or MATERIALS in possession of or developed by a PARTY created or generated after the EFFECTIVE DATE of this AGREEMENT.

MATERIALS means any tangible biological, chemical or physical materials.

PATENTS means all patent applications and patents and any reissues, re-examinations, patent term extensions, supplementary protection certificates or the like and any substitutions, confirmations, registrations or additions of or to any of the foregoing in any jurisdiction.

PATIENT MEDICAL RECORDS shall mean the INSTITUTION'S source documents which make up the patient medical records.

PROTOCOL shall mean protocol referred to in the applicable WORK ORDER hereto, as may be amended in accordance with this AGREEMENT.

REGULATORY AUTHORITY shall mean the statutory or governmental bodies with responsibility or who are authorized under the laws of the TERRITORY (as defined below) in relation to clinical studies (including without limitation the use of data arising out of clinical studies) to regulate the dissemination, importation, production or use of the STUDY PRODUCT including without limitation the relevant ethics committees with responsibility for clinical studies, and the U.S. Food and Drug Administration ("FDA") as applicable.

SERIOUS ADVERSE EVENT shall mean any or all of the following events: adverse event, adverse reaction, serious adverse event, serious adverse reaction or unexpected adverse reaction and the meaning of each such event shall be as defined in the PROTOCOL.

STUDY shall mean the Phase I, II, III, IV clinical study or project initiated and supported by SPONSOR and described in the applicable WORK ORDER to be conducted with the STUDY PRODUCT and in accordance with the PROTOCOL.

STUDY IP means any INTELLECTUAL PROPERTY contained in, based upon or deriving from the STUDY RESULTS.

STUDY PRODUCT shall mean the medicinal product, as defined in the WORK ORDER and the PROTOCOL, supplied by SPONSOR for use in the STUDY.

STUDY RESULTS means all INFORMATION and MATERIALS arising from the STUDY.

TERRITORY shall mean the United States where INSTITUTION and INVESTIGATOR shall perform the STUDY.

THIRD PARTY shall mean any person or entity other than the PARTIES and their AFFILIATES.

TRIAL MASTER FILE shall mean SPONSOR'S file containing the essential documents relating to the STUDY as required by the GCP GUIDELINES.

WORK ORDERS shall mean the specific details of each STUDY under this AGREEMENT, which have been separately negotiated and agreed upon between the PARTIES hereto and confirmed in writing using the form attached in APPENDIX I hereto and any Amendments to WORK ORDERS using the form attached in APPENDIX II hereto.

1 APPOINTMENT AND INCORPORATION OF WORK ORDERS

- 1.1 This AGREEMENT allows the PARTIES to contract for the conduct of multiple STUDIES through the execution of individual WORK ORDERS as more specifically described in this Article, without having to renegotiate the basic terms and conditions contained in this AGREEMENT. The specific terms and conditions applicable to each assignment will be defined in Schedules to the relevant WORK ORDER.
- 1.2 INSTITUTION hereby agrees to perform from time to time the STUDIES upon the terms and subject to the conditions of this AGREEMENT in general and the corresponding WORK ORDER and subsequent modifications (if any) in particular.
- 1.3 Each WORK ORDER and its subsequent modifications (if any) shall be subject to all the terms and conditions of this AGREEMENT. Should any terms or provisions of a WORK ORDER as modified (if any) conflict with the terms and provisions of this AGREEMENT, the terms and provisions of this AGREEMENT will prevail, except to the extent that a given WORK ORDER expressly and specifically stipulates the intention of the PARTIES to have a specific matter in a WORK ORDER supersede the terms and conditions of this AGREEMENT.

2 CONDUCT OF EACH STUDY

- 2.1 The INSTITUTION agrees to perform and will ensure that its employees working on the STUDY, including but not limited to INVESTIGATOR, will perform the STUDY in strict accordance with the applicable PROTOCOL which forms part of the applicable WORK ORDER and this AGREEMENT and may be amended from time to time, such amendments also forming part of the WORK ORDER and this AGREEMENT. The PROTOCOL will be provided to the INVESTIGATOR prior to the STUDY which fully details the clinical STUDY activities and responsibilities to be undertaken by the INSTITUTION and/or the INVESTIGATOR. In the event of a conflict between the terms of the PROTOCOL and this AGREEMENT, the PROTOCOL shall prevail with respect to the medical treatment of the patients and this AGREEMENT shall prevail with respect to all other matters.
- 2.2 The INSTITUTION agrees and will ensure that its employees working on the STUDY, including but not limited to INVESTIGATOR will:
 - (a) conduct this STUDY in compliance with all requirements of the INSTITUTION, any and all applicable laws, directives, rules, regulations, guidelines, professional standards, and codes of practice in the TERRITORY including those relating to the preparation, use and submission of data arising out of the STUDIES;
 - (b) fulfill their obligations to the applicable IRB in the TERRITORY where the STUDY is to be undertaken, and those required by INSTITUTION;
 - (c) submit all data and information based on the accrued recruitment of ENROLLED SUBJECTS to the STUDY, and undertake all activities, so that the time schedules set forth in the PROTOCOL and this AGREEMENT are met;
 - (d) at SPONSOR's reasonable expense, return all unused STUDY PRODUCTS, compounds, DEVICES, equipment, and related MATERIALS and all copies of CONFIDENTIAL INFORMATION, including CRFs and those MATERIALS that incorporate or otherwise record any STUDY IP to the SPONSOR within sixty (60) days of the earlier termination or completion of the STUDY. INSTITUTION may retain one copy of CONFIDENTIAL INFORMATION, in a secured location, solely for purposes of complying with this AGREEMENT;

(e) Complete Form FDA 1572 for each STUDY. The Form FDA 1572 will (a) be approved in form by SPONSOR, (b) list each location where the STUDY will be conducted, including any procedures and services required under the PROTOCOL, and (c) be signed by INVESTIGATOR.

3 CERTIFICATIONS AND REPRESENTATIONS

- 3.1 The INSTITUTION represents and certifies that:
- 3.2 The INSTITUTION and the INVESTIGATOR have the experience, capabilities, and resources including, but not limited to: (a) sufficient personnel and equipment; and (b) sufficient patients meeting enrolment criteria to efficiently and expeditiously perform the STUDY hereunder in a professional and competent manner and they will dedicate the necessary resources to perform the STUDY hereunder in such a manner. The INVESTIGATOR will thoroughly familiarize him or herself with the properties of the STUDY PRODUCT, the PROTOCOL, the latest version of the GCP Guidelines and any other applicable laws, regulations, and standard operating procedures prior to beginning the STUDY and ensure that the STUDY is conducted in compliance with the same.
- 3.3 The INSTITUTION, the INVESTIGATOR, and any of the INSTITUTION'S employees or other staff members performing the STUDY have such current licenses and permits as may be required to perform clinical studies and that none of them is now nor in the past ever been debarred or excluded from any national healthcare programs nor are any of them currently under investigation by the FDA for debarment action or license debarred pursuant to the U.S. Generic Drug Enforcement Act of 1992 (21 U.S.C. 301 et seq) or other national equivalent, and the INSTITUTION shall notify SPONSOR promptly in accordance with Article 17 (Notices) upon any inquiry concerning or the commencement of any such proceeding concerning any person performing the STUDY.
- 3.4 SPONSOR acknowledges that INSTITUTION, INVESTIGATOR and its/their employees may be conducting other clinical studies. INSTITUTION agrees and will ensure that INVESTIGATOR that they have no other STUDY obligations that would prevent them from performing their duties under this AGREEMENT.
- 3.5 SPONSOR understands that INSTITUTION may be involved in similar research through other researchers on behalf of itself and others. INSTITUTION shall be free to continue such research provided that it is conducted separately and it does not

create a conflict of interest with INSTITUTION's or INVESTIGATOR'S performance of their respective obligations under the STUDY, and SPONSOR shall not gain any rights via this AGREEMENT to such other research.

- 3.6 The INSTITUTION shall make available for review, prepare, modify, maintain, archive, retrieve and/or transmit, as may be applicable, any STUDY records and INFORMATION, including CRFs, medical records, informed consents, test results, or other source documents, in a manner acceptable for the collection of data for submission to, or review by, the FDA and other REGULATORY AUTHORITIES, and in full compliance with the PROTOCOL and all applicable laws. INSTITUTION shall make all PATIENT MEDICAL RECORDS of ENROLLED SUBJECTS available to SPONSOR, FDA and other REGULATORY AUTHORITIES for review.
- 3.7 If INSTITUTION uses SPONSOR's electronic data capture system for the collection of STUDY data, INSTITUTION agrees to the following: (i) notify SPONSOR promptly if an authorized user no longer requires access, (ii) return all SPONSOR hardware at the termination or conclusion of the STUDY, and (iii) ensure that computers used by STUDY staff for conduct of the STUDY have the necessary security systems, including but not limited to antivirus programs, firewalls, key software updates, secure access and are configured to prevent the disabling of security options, and (iv) allow SPONSOR access upon reasonable request, (v) ensure that employees maintain the confidentiality of their passwords, and (vi) electronic signatures, are the legally binding equivalent of handwritten signatures.
- 3.8 Any rights of access to INSTITUTION's facilities granted to SPONSOR under this AGREEMENT shall be subject to INSTITUTION's reasonable measures for purposes of confidentiality, safety, and security, and will be subject further to compliance with INSTITUTION's premises rules that are generally applicable to all persons at INSTITUTION's facilities.
- 3.9 This AGREEMENT does not involve the counselling or promotion of a business arrangement that violates state or federal law.

4 REPLACEMENT

4.1 In the event that INVESTIGATOR becomes either unwilling or unable to perform the duties required by this AGREEMENT, INSTITUTION will cooperate, in good faith and expeditiously, to find a replacement INVESTIGATOR with similar qualifications

acceptable to SPONSOR; however INVESTIGATOR shall continue to abide by all relevant obligations and conditions of this AGREEMENT following any replacement.

4.2 In the event a substitute INVESTIGATOR acceptable to the SPONSOR and the INSTITUTION is not found within a reasonable time period, the applicable WORK ORDER may be terminated in accordance with Article 10. The INSTITUTION'S cooperation in finding an acceptable replacement does not release it from its obligations to perform this AGREEMENT up to and including the effective date of termination.

5 TERM

This AGREEMENT shall be effective as of the EFFECTIVE DATE and shall continue until terminated in accordance with Article 10.

6 FEES AND PAYMENT

- 6.1 In consideration of the performance by INSTITUTION of the STUDY and associated obligations defined in an applicable WORK ORDER in accordance with the PROTOCOL, the SPONSOR will compensate the INSTITUTION in accordance with the payment schedule set out in the applicable WORK ORDER (subject to INSTITUTION'S compliance with the other terms of this AGREEMENT). If the INVESTIGATOR, or any other employee, or other staff member of the INSTITUTION, sees ENROLLED SUBJECTS at a location other than the location(s) agreed upon by the PARTIES for this STUDY, then any fees, costs, expenses or liabilities that arise from seeing ENROLLED SUBJECTS away from such location(s)) will be solely the responsibility of the INSTITUTION. The payment amounts set forth in each WORK ORDER may be modified only upon the prior written consent of the PARTIES. Likewise, non-emergency additional tests or services (e.g. tests or services not required by the PROTOCOL or performed in excess of PROTOCOL requirements) shall not be compensable hereunder without the prior written consent of the SPONSOR. The last payment under each WORK ORDER shall be made after the INSTITUTION completes all their obligations under the applicable WORK ORDER, and amongst other things, the SPONSOR has received all completed CRFs and all corresponding queries have been resolved.
- 6.2 The INVESTIGATOR acknowledges and understands that his judgment with respect to his medical advice to and care of each ENROLLED SUBJECT is not affected by the compensation INSTITUTION receives hereunder. The INVESTIGATOR shall use

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independent medical judgment in determining the eligibility of each ENROLLED SUBJECT to participate in each STUDY and as to all aspects of an ENROLLED SUBJECT's medical care.

- 6.3 The PARTIES hereto agree that compensation paid hereunder represents the fair market value of services rendered and that no part of any consideration paid pursuant to this AGREEMENT is a prohibited payment for the recommending or arranging for the referral of business or the ordering of items or services, nor are the payments intended to induce illegal referrals of business.
- 6.4 (a) Claims for services and/or products considered standard of care under the PROTOCOL and in connection with the STUDY that INSTITUTION and/or any INVESTIGATOR may submit for reimbursement to Medicare, Medicaid or other applicable government program (collectively "Medicare") or third-party payor shall at all times be in compliance with applicable laws including Medicare notices, issuances and national and local coverage decisions. If the SPONSOR or CRO provides any products or items for use in the STUDY at no charge to INSTITUTION and INVESTIGATOR, INSTITUTION agrees that it will not bill Medicare or other thirdparty payor for such products or items. INSTITUTION agrees and INVESTIGATOR understands that they will not bill Medicare or other third-party payor for any visits, services or expenses incurred during the STUDY for which they have received compensation from SPONSOR through CRO, or which are not part of the ordinary care they would normally provide for the patient.

(b) Due to legal requirements, SPONSOR may be required to disclose certain payments, gifts, and other transfers of value that it provides to health care providers, institutions and organizations. Accordingly, and notwithstanding any provision to the contrary, the compensation and other information hereunder may be publicly disclosed without notice by SPONSOR to comply with its legal obligations, regardless of whether such payment is remitted directly to INSTITUTION or INVESTIGATOR.

6.5 The INSTITUTION is the "PAYEE" under this AGREEMENT. The INSTITUTION acknowledges that it is accepting tax liability (if any) for the payments it receives for work performed under this AGREEMENT. Payment instructions shall be set forth in each applicable WORK ORDER.

6.6 The SPONSOR or its designated representative shall make payment in US dollars within thirty (30) days of receipt of the invoice by SPONSOR or its designated representative.

7 CONFIDENTIALITY AND NONDISCLOSURE

- 7.1 Each PARTY shall use the CONFIDENTIAL INFORMATION of the other PARTY solely for performing activities under this AGREEMENT and for a period of seven (7) years from the effective date of the applicable WORK ORDER shall hold such CONFIDENTIAL INFORMATION in confidence and not disclose or otherwise provide it to THIRD PARTIES without the prior written consent of the other PARTY which shall not be unreasonably withheld.
- 7.2 These requirements of non-use, confidentiality and non-disclosure shall not apply however to INFORMATION and/or MATERIALS which:
 - (a) a PARTY already knew of prior to disclosure hereunder as documented by prior written records; or
 - (b) is or becomes public knowledge other than by breach of this provision by a PARTY;
 - (c) a PARTY receives in good faith from a THIRD PARTY not in violation of an obligation of confidentiality; or
 - (d) a PARTY develops independently of any CONFIDENTIAL INFORMATION disclosed hereunder as documented by written records; or
 - (e) a PARTY is obliged to disclose in accordance with a regulatory submission or other requirement of law; if time permits, said PARTY shall first notify the other PARTY, so that it may seek a protective order or similar relief if appropriate or available, or
 - (f) is necessary to obtain IRB approval of the STUDY or that must be included in any ENROLLED SUBJECT'S written informed consent form; or
 - (g) is disclosed for the emergency medical care or treatment of an ENROLLED SUBJECT.
- 7.3 CONFIDENTIAL INFORMATION shall not be deemed to be within the foregoing exceptions merely because it is specific and embraced by more general information

in the public domain or in the possession of a receiving PARTY; or is a combination of information from multiple sources.

- 7.4 Each PARTY shall cause its agents, contractors, consultants and/or employees to comply with this obligation of confidentiality and shall take all reasonable steps to ensure the secrecy of such CONFIDENTIAL INFORMATION, including but not limited to disclosing such CONFIDENTIAL INFORMATION only to its personnel performing activities under this AGREEMENT who are bound by a comparable obligation of confidentiality.
- 7.5 Upon termination or expiration of this AGREEMENT, or earlier if so agreed in writing by the PARTIES, each PARTY shall either return all copies of the CONFIDENTIAL INFORMATION it may have received or destroy in a secure manner all such copies of the CONFIDENTIAL INFORMATION, if so instructed by the other PARTY, except each PARTY may retain one (1) copy of the other PARTY's CONFIDENTIAL INFORMATION for the purpose of establishing that PARTY's compliance with its obligations under this AGREEMENT.
- 7.6 All PARTIES shall keep confidential all protected health information ("PHI") from individual ENROLLED SUBJECTS and shall ensure that none could be identified in any reports, submissions or publications.

8 PUBLICATION AND RELEASE OF INFORMATION

8.1 The INSTITUTION shall recognize the integrity of a multi-site STUDY by not seeking to publish data derived from such work until the STUDY has been completed at all sites participating in the STUDY, or until SPONSOR has reported in full the STUDY RESULTS has been reported in full, or in the event that no such publication occurs within eighteen (18) months of the completion of the STUDY, the INSTITUTION shall be free to publish in accordance with the provisions of this Article.

The INSTITUTION reserves the right to publish the results of the STUDY generated by INSTITUTION in its conduct of the STUDY, provided however, that any such use of the STUDY RESULTS generated by the INSTITUTION in accordance with the PROTOCOL during the conduct of the STUDY will not result in a breach of INSTITUTION'S obligations of confidentiality. Prior to any publication related to the STUDY, INSTITUTION shall submit to the SPONSOR, for its review, a copy of any proposed abstract, manuscript, presentation or the like at least forty-five (45) days prior to the estimated date of submission for publication or other disclosure. If the

SPONSOR determines that the proposed publication contains patentable subject matter, the SPONSOR may require an additional delay of publication or other disclosure for a period of ninety (90) days for the purpose of filing patent applications or taking other appropriate action to protect its proprietary interests. If the SPONSOR determines that SPONSOR CONFIDENTIAL INFORMATION is contained in such manuscript or abstract, the INSTITUTION agrees to delete that information; provided however, that SPONSOR will permit INSTITUTION to publish STUDY RESULTS generated by the INSTITUTION, in accordance with the PROTOCOL, during the conduct of the STUDY to support its scientific conclusions included in the manuscript or abstract. For the avoidance of doubt, if no response is received by the INSTITUTION from the SPONSOR within such forty-five (45) day review period, publication may proceed. INSTITUTION's publication does not constitute a right of a subsequent publication of a manuscript, presentation or the like; any new publication or presentation must be submitted to SPONSOR for review in accordance with the terms herein. The participation of the SPONSOR shall be acknowledged in any publication or presentation unless written notice to the contrary is given.

8.2 SPONSOR may use, refer to, and disseminate reprints of scientific, medical, and other published articles relating to the STUDY which disclose the name of INVESTIGATOR and/or INSTITUTION, consistent with relevant copyright laws. Neither PARTY to this AGREEMENT shall use the other PARTY'S name in connection with any advertising or promotion of any product or service without the prior written permission of such PARTY. Both PARTIES agree that they will not disclose the terms of this AGREEMENT to any outside party without the permission of the other PARTY, except as required by applicable law.

9 INSPECTIONS

- 9.1 The INSTITUTION and/or INVESTIGATOR shall promptly notify the SPONSOR in writing of any inquiries, correspondence or communications with or from any REGULATORY AUTHORITY, including the FDA.
- 9.2 If any REGULATORY AUTHORITY, including the FDA requests permission to or does inspect the INSTITUTION's facilities or research records relating to this STUDY, the INSTITUTION will allow the SPONSOR to attend such inspections, and shall make all reasonable efforts to coordinate any scheduling of such inspections to permit SPONSOR to attend such inspections.

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- 9.3 The SPONSOR shall have the right itself or through a THIRD PARTY, upon reasonable prior written notice and during normal business hours, to audit the INSTITUTION where the STUDY is being performed, in accordance with Section 3.6.
- 9.4 The INSTITUTION will provide in writing to SPONSOR copies of all MATERIALS (to the extent that the MATERIALS can be physically copied into a writing), correspondence, statements, forms, and records which the INSTITUTION receives, obtains, or generates pursuant to any such inspection or in connection with any inquiries, communications or correspondence from any REGULATORY AUTHORITY including the FDA, for any STUDY under this AGREEMENT. The INSTITUTION will make reasonable efforts to segregate, and not disclose, any documents and the MATERIALS that are not required to be disclosed during such an inspection, including financial data and pricing information.

10 TERM and TERMINATION

- 10.1 This AGREEMENT shall expire seven (7) years from the EFFECTIVE DATE unless earlier terminated in accordance with this Section 10. The termination or expiration of this AGREEMENT shall not affect any open WORK ORDER. As to any open WORK ORDER, the terms and conditions and this AGREEMENT shall remain in full force and effect as to such open WORK ORDER. This AGREEMENT may be terminated by either PARTY at any time with or without cause upon thirty (30) days written notice.
- 10.2 Either PARTY shall have the right to terminate a specific WORK ORDER in subsection (a) below or this AGREEMENT in sub-section (b) below in its entirety forthwith, in the event:
 - (a) of a material breach of any WORK ORDER committed by the other PARTY which, if capable of being remedied, is not remedied within a period of thirty (30) days following the date of receipt of a written notice specifying the nature of the breach; and/or
 - (b) the other PARTY is dissolved or liquidated, files or has filed against it a petition under any bankruptcy or insolvency law, makes an assignment for the benefit of its creditors or has a receiver appointed for all or substantially all of its property, or experiences an event analogous to any of the foregoing in any jurisdiction in which any of its assets are situated.

- 10.3 An individual WORK ORDER may further be terminated by the following PARTIES prior to the completion date established in an applicable WORK ORDER on written notice if any of the following conditions occur:
 - (a) By any PARTY, effective immediately, if authorization to conduct the STUDY is not obtained or is withdrawn by the FDA or other REGULATORY AUTHORITY, ethics, or competent authority or if the emergence of any SERIOUS ADVERSE EVENT with the STUDY PRODUCT is of such magnitude or frequency in the opinion of either the INVESTIGATOR or SPONSOR to support termination;
 - (b) By the SPONSOR, effective immediately in accordance with Article 4 (Replacement) hereof;
 - (c) By the SPONSOR, effective immediately, if the INSTITUTION and/or INVESTIGATOR fails to perform the STUDY in accordance with the terms of the PROTOCOL, the latest version of GCP GUIDELINES, this AGREEMENT, or any other applicable laws, regulations, including FDA guidelines, or standard operating procedures, or the INSTITUTION becomes debarred or excluded from national programs or becomes subject to a threat of debarment or exclusion from national programs;
 - (d) By the SPONSOR, effective immediately, if it determines, in its sole discretion, that the INVESTIGATOR has failed to recruit or enroll a sufficient number of subjects for participation in the STUDY to make it likely that the statistical requirements applicable to the STUDY will be met;
 - (e) By the SPONSOR with or without cause, upon thirty (30) days written notice; or,
 - (f) By INSTITUTION upon thirty (30) days written notice if INVESTIGATOR becomes unable to perform or complete the STUDY.
- 10.4 In the event of termination of a WORK ORDER prior to completion of the STUDY pursuant to any of the sub-paragraphs of Article 10.3, the SPONSOR shall make a final payment for services actually performed in accordance with the STUDY BUDGET and for costs incurred through the date of termination, subject to the obligation of INSTITUTION to mitigate costs as far as reasonably possible. The SPONSOR will also reimburse INSTITUTION for reasonable, non-cancellable commitments properly incurred prior to the date of termination provided, however, UCB MSA The University of Texas System Sponsor-Initiated Clinical Trial Studies Effective for 7 years until August 13, 2020

that SPONSOR shall not be obligated to pay for non-cancellable commitments if a WORK ORDER is terminated pursuant to Article 10.3(c). In any of the above situations in which the SPONSOR has the right to terminate a WORK ORDER, or in which it reasonably believes that termination may be required, the SPONSOR shall have the right to suspend enrollment under the applicable WORK ORDER, or suspend performance of all or a part of the STUDY (subject to patient safety issues), while it determines whether termination is appropriate. Receipt of written notice of termination of the STUDY by the SPONSOR shall not release the INSTITUTION or the INVESTIGATOR from their obligations to perform a particular WORK ORDER up to and including the effective date of termination.

10.5 The termination of the AGREEMENT, for any reason whatsoever, shall not entail the termination of any on-going WORK ORDER, unless such WORK ORDER is also explicitly terminated in accordance with Article 10.2 and/or 10.3. Without prejudice to Article 1.3, the terms of the AGREEMENT shall continue to apply to any on-going WORK ORDER during and after the term of the AGREEMENT.

11 INTELLECTUAL PROPERTY

- 11.1 Nothing in this AGREEMENT shall affect a PARTY's rights to its BACKGROUND INTELLECTUAL PROPERTY nor imply grant of any license to a PARTY's BACKGROUND INTELLECTUAL PROPERTY unless expressly set forth herein.
- 11.2 INSTITUTION agrees and the INVESTIGATOR acknowledges that the SPONSOR owns all rights in and to the STUDY PRODUCT, DEVICE, the PROTOCOL, the STUDY RESULTS (subject to INSTITUTION'S publication rights as set forth in Article 8) and the STUDY IP. INSTITUTION and INVESTIGATOR, their respective agents, consultants, subcontractors and employees as the case may be shall, without delay, inform SPONSOR of any STUDY IP and hereby assign or shall cause to be assigned free of any restrictions and/or additional remuneration and charges, to SPONSOR all rights in and title to the STUDY IP. Upon SPONSOR's written request and at its sole expense, INSTITUTION and INVESTIGATOR and/or its agents consultants, subcontractors, and employees shall sign and deliver or shall cause, to be signed and deliver to SPONSOR all documents and shall do all such things as may be reasonably required to vest in SPONSOR as its sole and exclusive property the entire right, title and interest in and to all such STUDY IP. INSTITUTION agrees that it will not use any contractors or subcontractors in the conduct of any STUDY hereunder.

- 11.3 In the event that such assignment is not possible, for whatever reason, INSTITUTION and INVESTIGATOR hereby grant, or shall grant, or cause to be granted, as the case may be, to SPONSOR and its AFFILIATES an exclusive, worldwide, perpetual, irrevocable, unlimited, royalty-free and transferable license, with a right to sublicense, to the STUDY IP for any purpose.
- 11.4 The SPONSOR may, at its sole discretion and expense, prepare, file and prosecute one or more applications for statutory protection of the STUDY IP and defend and enforce such rights once obtained. In the case of patent applications, SPONSOR shall determine inventorship in compliance with applicable law. Upon SPONSOR's written request and at its sole expense, INVESTIGATOR and/or INSTITUTION, and their agents, consultants, subcontractors and employees shall reasonably assist SPONSOR in prosecuting such applications and execute and deliver any and all instruments necessary to make, file and prosecute all such applications. INSTITUTION agrees that it will not use any contractors or subcontractors in the conduct of any STUDY hereunder.
- 11.5 For the avoidance of doubt, the PATIENT MEDICAL RECORDS shall remain the property of the INSTITUTION. Other than a grant of a limited license to the INSTITUTION and INVESTIGATOR solely to permit them to carry out the STUDY hereunder, and a non-exclusive right to the INSTITUTION to use the STUDY RESULTS generated by INSTITUTION for its own internal non-commercial educational and research purposes, subject to the obligation of Article 7 (Confidentiality and Non-Disclosure), this AGREEMENT does not constitute any grant, option or license under any INTELLECTUAL PROPERTY rights of the SPONSOR.

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12 PRODUCT LIABILITY

- 12.1 The INSTITUTION and the INVESTIGATOR shall promptly notify the SPONSOR in writing of any claim of illness or injury which the INVESTIGATOR reasonably determines to be a SERIOUS ADVERSE EVENT to the STUDY PRODUCT or control drug, and shall, subject to the statutory duties of the Texas Attorney General, allow the SPONSOR to handle such claim (including settlement negotiations), and cooperate fully with the SPONSOR in its handling of the claim.
- 12.2 In accordance with SPONSOR'S regulatory obligations, SPONSOR shall promptly notify INSTITUTION of any relevant safety information that may (a) adversely affect the safety, health, or medical care of an ENROLLED SUBJECT, (b) affect the willingness of a ENROLLED SUBJECT to continue participation in the STUDY, or (c) alter the IRB's continuing approval of the STUDY. INSTITUTION shall promptly notify the IRB of any such events. INSTITUTION will consult with SPONSOR in preparing any communications to be provided to ENROLLED SUBJECTS. SPONSOR will be provided with copies of all communications prior to their dissemination. When an ENROLLED SUBJECT'S safety or medical care could be directly affected by STUDY RESULTS, INSTITUTION shall be free to provide the STUDY RESULTS to the ENROLLED SUBJECT in accordance with IRB policy.

13 INDEMNIFICATION

- 13.1 SPONSOR shall indemnify and hold harmless the INSTITUTION, SYSTEM, their Regents, officers, employees and agents acting on its behalf for STUDY related services, including without limitation the INVESTIGATOR, from any liability, loss, or damage they may suffer as a result of claims, demands, costs, or judgments against them arising out of the bodily injury including death of an ENROLLED SUBJECT directly related to the administration of the STUDY PRODUCT(s) or DEVICE or properly performed procedures required by the PROTOCOL, or the use by SPONSOR of the STUDY RESULTS so long as the STUDY RESULTS are generated by INSTITUTION in accordance with the PROTOCOL under the applicable WORK ORDER.
- 13.2 The SPONSOR'S obligation of indemnification shall not apply to the extent the loss is the result of:

- (a) the terms of the PROTOCOL or any written instruction relative to the administration of the STUDY PRODUCT(s) or DEVICE are not strictly adhered to; or
- (b) the INSTITUTION and/or INVESTIGATOR failed to use reasonable medical judgement in the administration, or in the control of the administration of the STUDY PRODUCT(s) or DEVICE; or
- (c) the INSTITUTION and/or INVESTIGATOR failed to comply with applicable national, state and local laws, or to conduct the STUDY in accordance with FDA regulations and the latest applicable GCP GUIDELINES; or
- (d) the damage is attributable to the negligent act, omission or wilful misconduct on the part of the INSTITUTION, its staff members and/or INVESTIGATOR involved in the STUDY; or
- (e) the INSTITUTION failed to provide SPONSOR prompt written notice of any claims involving the STUDY PRODUCT(s) or DEVICE and does not cooperate fully with SPONSOR in the defence thereof including, but not limited to, allowing SPONSOR complete access to all relevant records. INSTITUTION's cooperation is subject to the statutory duties of the Texas Attorney General; or
- (f) the INSTITUTION and/or INVESTIGATOR made any admission or took any other action (or omits to take any action) that could prejudice the conduct of any action or claim, provided that this provision shall not be breached if the INSTITUTION and/or INVESTIGATOR can demonstrate that it has acted in accordance with its internal complaint, accident reporting or disciplinary procedures or where any statement or action is required by law; or
- (g) unauthorized warranties made by the INSTITUTION and/or the INVESTIGATOR concerning the STUDY PRODUCT or DEVICE; or
- (h) in any case in which written informed consent was not obtained for the ENROLLED SUBJECT involved in accordance with the PROTOCOL.
- 13.3 The SPONSOR shall secure and maintain in full force and effect throughout the performance of the STUDY an insurance policy providing sufficient coverage in respect of its potential liability under this AGREEMENT, as is usual and customary in the pharmaceutical industry to procure.

- 13.4 The INSTITUTION, to the extent authorized under the Constitution and the laws of the State of Texas, shall indemnify and hold the SPONSOR and its AFFILIATES harmless from, any loss, claim, or demand arising from the negligent acts, omissions or wilful misconduct on the part of the INSTITUTION and/or the INVESTIGATOR in the performance of the research activities in accordance with the PROTOCOL, the terms of this AGREEMENT or any WORK ORDER; provided, however, that INSTITUTION shall not hold SPONSOR harmless from claims arising out of the negligence or wilful malfeasance of SPONSOR and its AFFILIATES, or any person or entity not acting under INSTITUTION's supervision or control.
- 13.5 The INSTITUTION, as a member institution of SYSTEM, is an agency of the State of Texas and is self-insured pursuant to The University of Texas System Professional Medical Liability Benefit Plan, under the authority of Section 59.01, Texas Education Code. INSTITUTION has and will maintain in force during the term of this AGREEMENT adequate insurance to cover its indemnification obligations hereunder, and will provide SPONSOR, upon written request, with a certificate of insurance therefore.
- 13.6 INSTITUTION shall arrange or provide medical care should an ENROLLED SUBJECT suffer a bodily injury as a direct result of the STUDY PRODUCT or DEVICE or any properly performed procedures required by the PROTOCOL. SPONSOR will pay for all reasonable and necessary medical and hospital costs required for the treatment of the bodily injury, only to the extent: i) is not part of ENROLLED SUBJECT's natural progression of the disease being studied, ii) that bodily injury is due not to ENROLLED SUBJECT's other pre-existing condition(s), iii) it is not a result of INSTITUTION'S negligence or willful misconduct, or iv) it is not due to INVESTIGATOR's failure to follow the PROTOCOL.

14 DATA AND SAFETY REPORTS

In accordance with SPONSOR'S regulatory obligations SPONSOR shall provide to INSTITUTION an annual report of any SERIOUS ADVERSE EVENTS and INSTITUTION shall report that information to its own IRB.

15 RECORDS MAINTAINANCE

STUDY records should be maintained as set forth in the PROTOCOL and as required by applicable law or regulation, whichever is longer.

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16 ENTIRE AGREEMENT

The PARTIES agree that this AGREEMENT, each applicable WORK ORDER, the final PROTOCOLS and any attachments and appendices hereto constitute the sole, full, and complete AGREEMENT by and between the INSTITUTION and the SPONSOR and supersede all other written and oral agreements and representations between the INSTITUTION and the SPONSOR with respect to the STUDY. No amendments, changes, additions, deletions, or modifications to or of this AGREEMENT shall be valid unless reduced to writing and signed by the PARTIES.

17 NOTICES

Any requests for changes or amendments or other notices or communications concerning this AGREEMENT should be in writing and shall be deemed to have been given when mailed by postage prepaid or bonded courier and forwarded to the following:

To SPONSOR:

UCB BIOSCIENCES, INC.

Attn: Global Head of Outsourcing & Contracts 8010 Arco Corporate Drive, Suite 100 Raleigh, NC 27617

To INSTITUTION: See Attachment 1

18 SURVIVAL

This AGREEMENT shall be binding upon the PARTIES, their legal representatives, successors and assigns. The obligations of the PARTIES contained in the PROTOCOL and Articles 7 (Confidentiality and Nondisclosure), 8 (Publication and Release of Information), 9 (Inspections), 11 (Intellectual Property), 12 (Product Liability), 13 (Indemnification), and 18 (Survival), 19 (Financial Disclosure), and 20 (Governing Law) shall survive the termination or expiration of this AGREEMENT as shall such other terms and provisions as by their nature or intent should survive.

19 FINANCIAL DISCLOSURE

19.1 The INSTITUTION hereby agrees that, for each listed or identified INVESTIGATOR or sub-INVESTIGATOR who is directly involved in the treatment or evaluation of research subjects (e.g., each INVESTIGATOR or sub-INVESTIGATOR listed on the UCB MSA - The University of Texas System Sponsor-Initiated Clinical Trial Studies Effective for 7 years until August 13, 2020 Form 1572 or any analogous national or device-related form or list), it shall have INVESTIGATOR or sub-INVESTIGATOR promptly send to the SPONSOR, a copy of the Financial Disclosure by Clinical Investigators Form that has been fully completed and signed by such INVESTIGATOR or sub-INVESTIGATOR.

- 19.2 No payments will be provided pursuant to this AGREEMENT until the SPONSOR has received a completed, signed form for each INVESTIGATOR.
- 19.3 The INSTITUTION agrees to ensure that all such forms are promptly updated, as needed, to maintain their accuracy and completeness during the term of this AGREEMENT and for one (1) year following completion of the STUDY. The INSTITUTION further agrees to assist the SPONSOR in obtaining analogous completed, signed forms for each such INVESTIGATOR and sub-INVESTIGATOR one year after completion of the STUDY, and to assist in obtaining any information and executing any documents necessary to fully comply with 21 CFR part 54, or any rules or regulations there under or analogous national regulations. The INSTITUTION acknowledges and agrees that the completed forms may be subject to review by governmental or regulatory agencies.

20 GOVERNING LAW

This section is intentionally left blank.

21 RELATIONSHIP BETWEEN THE PARTIES

The INSTITUTION shall act as an independent contractor of the SPONSOR and shall not be construed for any purpose as the partner, agent, employee, servant, or representative of the SPONSOR. The SPONSOR shall not be responsible for any employee benefits, pensions, employer liability insurance, withholding, or employment-related taxes of the INSTITUTION. The INSTITUTION shall not enter into any contract or agreement with a THIRD PARTY that purports to obligate or bind the SPONSOR and the SPONSOR shall not enter into any contract or agreement with a THIRD PARTY that purports to obligate or bind the SPONSOR and the SPONSOR shall not enter into any contract or agreement with a THIRD PARTY that purports to obligate or bind the INSTITUTION. The INSTITUTION and INVESTIGATOR acknowledge that SPONSOR may perform its obligations hereunder either itself or through a THIRD PARTY.

22 WAIVER AND SEVERABILITY

Failure to insist upon compliance with any of the terms and conditions of this AGREEMENT shall not constitute a general waiver or relinquishment of any such

terms or conditions. If any part of this AGREEMENT is held unenforceable, the rest of the AGREEMENT will nevertheless remain in full force and effect.

23 NO ASSIGNMENT

The INSTITUTION shall not assign or subcontract any of its rights or obligations under this AGREEMENT or any WORK ORDER without the written consent of the SPONSOR. The SPONSOR shall have the right to assign or transfer this AGREEMENT in whole or in part upon written notice to INSTITUTION and INVESTIGATOR.

24 EXECUTION

This AGREEMENT shall not be considered accepted, approved, or otherwise effective until signed below by the appropriate PARTIES. Each of the PARTIES hereto represents and certifies that the person signing below on such PARTY's behalf has the authority to enter into this AGREEMENT, and that this AGREEMENT does not conflict with any existing agreement or obligation of such PARTY in such a way as to breach that agreement or prevent performance hereunder. The INSTITUTION and/or INVESTIGATOR further represent that the PAYEE (as defined in Section 6.5 above) designated herein is the proper payee for this AGREEMENT.

[REMAINDER OF PAGE INTENTIONALLY LEFT BLANK]

IN WITNESS WHEREOF, the PARTIES have caused this AGREEMENT to be executed by their duly authorised representatives.

Done in two copies, each PARTY having received its copy.

UCB Biosciences, Inc.

UCB Biosciences, Inc.

Bv_s

Name: Jonstance Hopkins Associate Director Titleor Site Contract Management Date: 30 Aug 2013

The University of Texas Health Science Center at Tyler:

By:

Allan

Name: David Anderson Title: Director, Pre-Award Services

Date:

The University of Texas Health Science Center at San Antonio:

By: Jane A. Youngers Name:

Title: Asst. Vice Pres. for Research Admin. Title:

Date: 08-26-2013

By:

Name: Global Head of 0 & C

Title:

Date: 2013

The University of Texas Health Science Center at Houston:

By:

Name: Karen S. Niemeier Assistant Director, Contracts Title: Office of Sponsored Projects Date: 8/19/2013

The University of Texas Southwestern Medical Center:

sel RCharbonea Wisten By:

Name: Angela R. Charboneau Wishon, JD

Vice President, Research Administration 8-21-2013

UCB MSA - The University of Texas System Sponsor-Initiated Clinical Trial Studies Effective for 7 years until August 13, 2020 Date:

The University of Texas At Austin:

By: **Bill Catlett** Name: Director Office of Industry Engagement Title:

AUG 2 8 2013 Date:

The University of Texas Medical Branch at Galveston:

By:

Name:

Susan E. Ramsey, CRA **Manager of Research Operations** Title:

Date:

ATTACHMENT 1

David Hawkins Associate Director Office of Sponsored Projects The University of Texas at Austin 101 E. 27 th Street North Office Bldg., Suite 5.300 Austin, TX 78712 Phone: 512-471-6424 Fax: 512-471-6564 Tax ID: 74-6000203	Angela R. Charboneau Wishon, J.D. Vice President for Research Administration The University of Texas Southwestern Medical Center 5323 Harry Hines Blvd. Dallas, Texas 75390-9105 Phone: 214-648-6449 Fax: 214-648-4474 Tax ID: 75-6002868
Jane A. Youngers Assistant Vice President for Research Administration The University of Texas Health Science Center at San Antonio 7703 Floyd Curl Drive, Mail Code 7828 San Antonio, TX 78229-3900 Phone: 210-567-8107 Fax: 210-567-2344 Tax ID: 74-1586031	Karen Niemeier Director, Contracts The University of Texas Health Science Center at Houston P.O. Box 20036 Houston, TX 77225 Overnight address: 7000 Fannin Street, Suite 1006 Houston, TX 77030 Phone: 713-500-3999 Fax: 713-383-3746 Tax ID: 74-1761309
David Anderson Director, Office of Pre-Award Services The University of Texas Health Science Center at Tyler 11937 U.S. Hwy. 271 Tyler, TX 75708-3154 Phone: 903-877-7486 Fax: 903-877-7558 Tax ID: 75-6001354	Susan Ramsey Manager of Research Operations The University of Texas Medical Branch at Galveston Office of Sponsored Projects 301 University Boulevard 4.400 Rebecca Sealy Hospital Galveston, TX 77555-0156 Phone: 409-266-9482 Fax: 409-266-9470 Tax ID: 74-6000949

APPENDIX I – WORK ORDER Form

UCB Biosciences, Inc.

[Insert name of Institution]

UCB STUDY PRODUCT or DEVICE	AND STUDY/PROTOCOL
No	

This Work Order ("WORK ORDER") is between UCB BIOSCIENCES, INC. ("SPONSOR") and ______ ("INSTITUTION") and relates to the Master Clinical Trial Agreement between UCB and INSTITUTION dated ______ (the "AGREEMENT").

Pursuant to the AGREEMENT, INSTITUTION has agreed to perform STUDY or STUDIES in accordance with written WORK ORDERS, such as this one, entered into from time to time describing such STUDY or STUDIES.

This WORK ORDER is executed pursuant to <u>Section 1</u> of the AGREEMENT. The terms of the AGREEMENT and the PROTOCOL (as defined below) are deemed incorporated herein as if fully restated, and shall prevail in the event of any internal conflict between the AGREEMENT or the PROTOCOL and this WORK ORDER, except as expressly stated herein. Capitalized terms used herein shall have the meaning specified in the AGREEMENT unless otherwise defined herein.

SPONSOR AND INSTITUTION HEREBY AGREE AS FOLLOWS:

- This document constitutes a "WORK ORDER" under the AGREEMENT and this WORK ORDER and the services contemplated herein are subject to the terms and provisions of the AGREEMENT.
- 3. [Insert name of principal investigator] ("INVESTIGATOR") shall, on INSTITUTION's behalf, serve as INVESTIGATOR for the STUDY and is employed by INSTITUTION.
- 4. INSTITUTION and the INVESTIGATOR have reviewed sufficient information regarding the STUDY PRODUCT and the PROTOCOL to evaluate their interest in participating in the STUDY.

- 5. The INSTITUTION and the INVESTIGATOR shall perform the STUDY in strict accordance with the protocol entitled, "_____" ____ STUDY, dated _____ day of ______, and its amendments (the "PROTOCOL"). The PROTOCOL has previously been provided to the INVESTIGATOR and fully details the clinical research activities and responsibilities to be undertaken with all due diligence by the INSTITUTION and/or the INVESTIGATOR.
- 6. This WORK ORDER shall commence on the last date of signature hereof and shall continue until close-out of the INSTITUTION and completion of all obligations herein, including receipt by SPONSOR of all ENROLLED SUBJECT data and any corresponding queries in a form acceptable to SPONSOR, unless terminated earlier in accordance with Article 10 of the AGREEMENT.
- 7. SPONSOR has engaged ______ ("CRO") to act as an independent contractor, but not as a party to this AGREEMENT and this WORK ORDER, to carry out on behalf of SPONSOR certain aspects of SPONSOR's responsibilities hereunder, which may include, but are not limited to, contract execution, payment, monitoring and/or other STUDY activities.
- 8. All notices specific to this WORK ORDER shall be in writing. They shall be deemed given the sooner of receipt or three (3) business days after having been posted. They shall be addressed to the following address:

if to INSTITUTION:

With a copy to INVESTIGATOR:

if to SPONSOR:

UCB [insert entity and address and UCB STUDY CPM name here]

Copy to:

UCB Biosciences, Inc.

8010 Arco Corporate Drive, Suite 100 Raleigh, NC 27617 Attention: Constance Hopkins Associate Director, Head of Site Contracts Management

9. PAYMENT SCHEDULE AND BUDGET

A. PAYMENT TERMS

CRO on behalf of SPONSOR will reimburse INSTITUTION in United States Dollars (USD) Reimbursements will be calculated on a completed visit per ENROLLED quarterly. SUBJECT basis in accordance with the attached Budget, unless otherwise noted in the per subject budget. Ninety percent (90%) of each payment due, including Screening Failure Visits and Unscheduled Visits (see Articles below), will be made based upon prior guarterly enrollment data confirmed by ENROLLED SUBJECT Case Report Forms (CRFs) received from the INSTITUTION supporting ENROLLED SUBJECT visitation. The balance of monies earned, up to ten percent (10%), will be pro-rated upon verification of actual ENROLLED SUBJECT visits, and will be paid by CRO on behalf of SPONSOR to the INSTITUTION upon final acceptance by CRO of the CRF pages, all data clarifications issued, the receipt and approval of any outstanding regulatory documents as required by SPONSOR, the return of all unused supplies to SPONSOR, and upon satisfaction of all other applicable conditions set forth in this WORK ORDER. If any money already paid to INSTITUTION by CRO exceeds the final payment amount, the difference shall be returned promptly by INSTITUTION to CRO, within thirty (30) days of receipt of invoice.

CRFs will qualify for payment based on ENROLLED SUBJECT status as follows:

Visits completed per PROTOCOL, fully payable;

Discontinued due to SERIOUS ADVERSE EVENTS, prorated for the number of completed visits;

• Other discontinuation or ENROLLED SUBJECT lost to follow up; prorated for the number of completed visits.

CRFs will not qualify for payment as follows:

Major, disqualifying PROTOCOL violation.

B. SCREENING FAILURE PAYMENTS:

Screen failures for the STUDY are defined as STUDY subjects that are screened but could not be randomized as defined in the PROTOCOL. The INSTITUTION will be compensated for [CRO to insert protocol specific screen failure reimbursement – subject to UCB STUDY CPM and O&C Representative approval] of randomized subjects whichever is higher. This only applies to assessments associated with screening (once the subject's consent has been obtained) as opposed to pre-screening (e.g. reviewing medical charts, clinic records etc). INSTITUTION will be reimbursed at a flat rate of [CRO to insert the amount of V1 here – subject to UCB STUDY CPM and O&C Representative approval] for each eligible screen or baseline failure. INSTITUTION agrees to use reasonable efforts to select appropriate STUDY subjects.

To be eligible for reimbursement of such screening visit, INSTITUTION must: (i) submit to CRO completed screening failure CRF pages and any additional information, which may be requested by CRO to appropriately document the patient screening procedures, (ii) employ reasonable screening procedures and processes to ensure that only appropriate subjects are entered into the screening process, and (iii) have proper documentation available for verification, if requested. Sponsor has the right to reduce or cease the screening failure payments, in its sole discretion, upon its review of the documentation relating to the subjects entered into screening and the screening procedures performed. Furthermore, such payments will be subject to Sponsor approval and the other terms and conditions, if any, set forth herein.

C. UNSCHEDULED VISITS:

CRO on behalf of SPONSOR will pay INSTITUTION for unscheduled visits according to the procedures required by the PROTOCOL and performed at said visit as documented by completed and entered CRF modules and any additional information that SPONSOR may request to appropriately document the procedures performed. Once the completed CRF and any additional information which may be requested by SPONSOR to appropriately document the procedures performed and accepted by SPONSOR, payment for the unscheduled visit will be included in the scheduled quarterly payment.

D. IRB PAYMENTS:

IRB costs will be reimbursed on a pass-through basis and are not included in the attached budget. Any subsequent re-submissions or renewals, upon approval by SPONSOR, will be

reimbursed upon receipt of appropriate documentation. Payment of non-refundable IRB fees shall be made upon receipt of invoice.

E. ORIGINAL INVOICES FOR PAYMENTS:

Original invoices pertaining to the STUDY shall include the STUDY number [insert UCB Study Number] and should be submitted to CRO for reimbursement as follows:

UCB BIOSCIENCES, INC.

c/o [CRO]

[CRO to insert appropriate entity and address]

F. INSTITUTION'S PAYMENT ADDRESS:

G. OTHER PAYMENTS:

NO OTHER ADDITIONAL FUNDING REQUESTS WILL BE CONSIDERED WITHOUT THE CONSENT OF CRO and /or SPONSOR.

H. PER SUBJECT BUDGET

Such payment, as described within this Section will not be made to the INSTITUTION for any milestone that is not achieved as defined hereto.

[CRO to insert the excel budget - on next page]

IN WITNESS WHEREOF, the PARTIES have caused this WORK ORDER to be executed by their duly authorized representatives.

Done in three copies, each PARTY having received its copy

UCB BIOSCIENCES, INC.:	UCB BIOSCIENCES, INC .:
Ву:	Ву:
Name:	Name:
Title:	Title:
Date:	Date:
INSTITUTION:	
Ву:	
Name:	

INVESTIGATOR:

Date:

Title:

I acknowledge that I have read the terms and conditions of the AGREEMENT and this WORK ORDER and shall abide by the provisions of the AGREEMENT and this WORK ORDER as though I were a party hereto.

By:	······
Name:	
Date:	

APPENDIX II

WORK ORDER AMENDMENT FORM

AMENDMENT No. _____

STUDY/PROTOCOL No.

This amendment #X ("Amendment") effective as of the final signature date is between UCB BIOSCIENCES, INC. with an address at 8010 Arco Corporate Drive, Suite 100, Raleigh, NC 27617 ("SPONSOR"), and ______ with an address at

("INSTITUTION") and relates to WORK ORDER No._____ with the Effective Date of XX ("WORK ORDER") under the supervisions of [Insert INVESTIGATOR's name here] ("INVESTIGATOR") between SPONSOR and INSTITUTION, hereinafter individually referred to as a "PARTY" or together referred to as the "PARTIES".

WHEREAS, the PARTIES desire to amend and modify the WORK ORDER as set forth below in order that the WORK ORDER, as amended and modified, is acceptable to all PARTIES for execution;

THEREFORE, in consideration of the premises and of the mutual covenants herein, the PARTIES agree that the WORK ORDER shall be and is hereby amended and modified as follows:

1. Overview of the changes associated with this Amendment:

1.1 List of WORK ORDER changes:

2. If the terms of the WORK ORDER in any way conflict with or are otherwise inconsistent with the terms of this Amendment, this Amendment shall govern and control unless specifically stated otherwise.

3. All other terms of the WORK ORDER remain in full force and effect.

IN WITNESS WHEREOF, the PARTIES hereto have executed this Amendment as of the last day and year first written below.

ACCEPTED AND AGREED TO:

UCB BIOSCIENCES, INC.:	UCB BIOSCIENCES, INC.:
Ву:	By:
Name:	Name:
Title:	Title:
Date:	Date:
INSTITUTION:	Ву:

Name:	
Title:	
Date:	

READ AND UNDERSTOOD

INVESTIGATOR:

By:

Name: _____

Date: