Maine Medical Center
CLINICAL STUDY AGREEMENT
STANDARD CONTACT LANGUAGE/CHECKLIST

_____ **Institution/Investigator Identity**

This Agreement is made between _____, a company organized under the laws of the having a place of business at_____ ("Sponsor") and Maine Medical Center**,** a non-profit corporation organized and existing under the laws of the State of Maine with a principal place of business at 22 Bramhall Street, Portland, ME 04102-3175 ("Institution"), and _____ with an office at _____("Investigator").

Institution, through Principal Investigator, agrees to conduct a clinical study entitled, _____ in accordance with this Agreement, good clinical practice and the highest medical standards, and all applicable laws, rules, regulations and guidelines relating to the conduct of clinical investigations, including 21 CFR Parts 50, 54, 56 and 312.

In the event of any conflict between the Protocol and the provisions of this Agreement, the Protocol shall govern with respect to scientific and subject informed consent issues, and the provisions of the Agreement shall govern with respect to all other issues. In the event of any conflict between the informed consent document and the provisions of this Agreement with respect to any commitment by the Sponsor to cover costs associated with subject injuries, the broader commitment that is more protective of human subjects shall control.

_____ **Access to Patient Medical Records**

When seeking access to patient medical records or reports that include patient-identifiable information, the following provision is required:

. . . provided, however, that access to patient medical records shall be conditioned upon appropriate patient authorization unless otherwise provided by law.

_____ **Adverse events**

Required provision

Investigator agrees to promptly report all adverse events that occur during the course of the study according to Institutional polices and federal guidelines. Sponsor agrees to notify Institution/Principal Investigator according to FDA regulations, including up to two years post-study closure, of any information such as Study results or findings from a Study monitoring visit that could affect the safety or medical care of current or former Study subjects, affect current subject willingness to continue participation, influence the conduct of the study or alter the IRB's approval. Sponsor and Institution shall comply with their respective reporting requirements to regulatory authorities, including the FDA, OHRP and other authorities, as required. Institution, through the Principal Investigator, shall be responsible for informing study subjects of such information received from the sponsor.

____ **Confidentiality**

Our preferred position is that our obligation to maintain the confidentiality of information provided by the Sponsor shall be limited to 3 years beyond the term or extension of the Agreement.

_____ **Limits of Confidentiality**

Our preferred provision addressing the definition of confidential information and exceptions to the confidentiality obligation are as follows:

Sponsor acknowledges that Institution/Investigator may disclose proprietary or Confidential information, materials and/or data of the Sponsor (hereinafter collectively referred to as "Confidential Information") with institutional staff for the purpose of approval and proper conduct of this Study. Sponsor will use reasonable best efforts to mark any documents containing Confidential Information as "Confidential" and to reduce any orally disclosed Confidential Information to writing within thirty (30) days following disclosure. It is agreed that failure to mark documents or reduce oral disclosures to writing shall not alleviate Institution of its obligations under this Section ___ if the disclosed information would reasonably be considered confidential based upon the nature of the information or the circumstances surrounding the disclosure. During and after this Study, Institution/Investigator shall keep confidential and not use Confidential Information for any purpose other than one related to this Study. The Provisions in Section __ shall not apply to any Confidential Information disclosed hereunder which:

(a) was known or used by the Institution/Investigator prior to its date of disclosure by Sponsor, as evidenced by their prior written records;
(b) is lawfully disclosed to the Institution/Investigator either before or after the date of the disclosure by Sponsor, without an obligation of confidentiality by sources (other than the Sponsor) rightfully in possession of the confidential information;
(c) becomes published or generally known to the public, either before or after the date of the disclosure to Institution/Investigator through no fault or omission on the part of the Institution/Investigator;
(d) is independently developed by or for the Institution/Investigator without reference to or reliance upon the Confidential Information; or
(e) is required to be disclosed by Institution/Investigator to comply with applicable laws, to defend or prosecute litigation or to comply with governmental regulations, provided that the Institution/Investigator provides prior written notice of such disclosure to Sponsor and takes reasonable and lawful actions to avoid and/or minimize the degree of such disclosure.

_____ **Governing Law**

Our preferred provision

This Agreement shall be governed by and construed and interpreted in accordance with the laws of the State of Maine and each of the parties hereby submits to the jurisdiction of the courts of the State of Maine, both state and federal.

_____ **HIPAA**

The confidentiality of patient records and patients' protected health information shall be maintained at all times by all parties. Unless otherwise permitted by applicable law, all parties to this Agreement will not use or disclose patients' protected health information in violation of the requirements of 45 CFR 164.504 and 164.506(e)1, known as the Health Insurance Portability and Accountability Act (HIPAA) which are incorporated herein by reference. All parties agree to comply with applicable HIPAA standards in all respects, including implementation of all necessary safeguards to prevent such disclosure and the assurance that any subcontractors or agents to whom either party has provided such protected health information agree to the same restrictions and conditions imposed on the parties hereto under HIPAA.

_____ **Human Research Protection Program**

In the event that MMC does not hold the contract for a given clinical study and the Principal Investigator is not an employee of MMC, however, the Investigator wants to engage the services of a float pool study coordinator and/or grant accountant, a separate Letter of Agreement shall be developed between MMCRI and the Investigator and/or his Practice and will include language to the effect that the Investigator will abide by MMC's Human Research Protection Program and that the study will be reviewed by MMC's IRB.

IRB Approval

Required provision:

In the event that this Study is not approved by Institution's IRB, then this Agreement shall be null and void.

_____ **IRB Fee**

Required provision:

In addition to the fees for evaluable Study participants, a one time IRB processing fee of $2,000 for Full Board approval or $500 for Expedited Board approval will be made to compensate for all expenses associated with obtaining Institutional IRB approval.

_____ **Indemnification by Sponsor**

Preferred provision:

Sponsor, its successors and assigns, hereby agrees to indemnify and hold harmless Institution/Investigator and its employees and servants, including but not limited to the Institutional Review Board and its members, and their successors and assigns, from any claim, costs, liability and expense arising from or attributable to any acts or omissions of the servants or employees of Sponsor in performing services pursuant to this Agreement.

Institution, its successors and assigns, hereby agrees to indemnify and hold harmless Sponsor, its employees and servants, and their successors and assigns, from any claim, costs, liability and expense arising from or attributable to any acts or omissions of the **servants*** or employees of Institution in performing services pursuant to this Agreement.

Continued on next page…

Indemnification by Sponsor, continued…

If no indemnification provision, confirm in writing that this is observational study

*Servants would be individuals specifically under contract to MMC who we are agreeable to cover under the indemnification provision for their actions; we will not provide indemnification coverage for independent contractors (non-employed Medical Staff)

If PI is non-employed physician of Site: Alternative: Site, its successors and assigns, hereby agrees to indemnify and hold harmless Sponsor, its successors and assigns, from any claim, costs, liability and expense arising from or attributable to any acts or omissions of the servants or employees of Site, the Principal Investigator and any Co-Investigators in performing services pursuant to this Agreement, except to the extent that any non-employed physician professional liability policy provides primary coverage for any such claim, costs, liability and expense.

_____ **Infringement Indemnification by Sponsor**

Sponsor warrants to Institution/Investigator that it is the developer and sole owner of, or has the right to grant the license of use and provide ongoing service for any intellectual property transferred to Institution/Investigator pursuant to this Agreement. Sponsor, its successors and assigns, hereby agrees to indemnify and hold harmless Institution/Investigator, its successors and assigns, from any claim, costs, liability and expense arising from or attributable to any claim contesting ownership or asserting infringement based upon any intellectual property transferred or provided to Institution/Investigator pursuant to this Agreement.

_____ **Insurance**:

Maine Medical Center's position in clinical trial agreements is that the cost of a study subjects' medical treatment for adverse reactions should be borne by the Study sponsor; it is not appropriate to ask the subject's insurance carrier to defray such costs when they are attributable to participation in the study and not to the underlying disease or condition being treated. If the sponsor proposes the inclusion of language to the effect that the sponsor is only obligated to pay for such treatment if the subject's own insurance does not cover the treatment, MMC cannot accept such language. It is not a sufficient solution for the agreement to imply that we are to seek third party coverage and for the sponsor to accept our false statement that third party coverage was denied when we did not in fact seek such coverage. In this case, language should be included that states "however, Sponsor will not require the Study participant, Institution or Investigator to first seek coverage by the Study participant's insurance or other third party coverage". This compromise language is one that MMC has accepted on some occasions – (ie we will not look for the sponsor for such costs to the extent they are covered by third party insurance, but that we are under no obligation to seek third party coverage). This language assures that there will be no double billing but we avoid the hassle and delay of seeking third party coverage and only getting reimbursement from the sponsor after such coverage is denied.

_____ **Non-employed Physician**

When the Principal Investigator is not a Maine Medical Center employee, the following provision is required:

_____, M.D./D.O., as a non-employed physician of Institution, including any non-employed physician who may be treating Study participants, shall maintain in full force and effect at his/their own cost and expense during the term of this Agreement, malpractice insurance, but only insofar as activities under this Agreement are concerned.

_____ **Notices**

Preferred provision:

All notices and communications required or permitted under this Agreement shall be deemed sufficiently served if hand delivered or served by certified mail, postage prepaid, and addressed as follows:

To Institution: Maine Medical Center
22 Bramhall Street
Portland, ME 04102-3175
Attn: Donald L. St. Germain, M.D., Associate VP/Research;

With a copy to MaineHealth
465 Congress Street, Suite 600
Portland, ME 04101-3537
Attn: Donald E. Quigley, Esq., Vice President, Legal Affairs

To Principal Investigator:

To Sponsor: _____

_____ **Proprietary Information**

The existing inventions and technologies of Sponsor or the Institution and Investigator are their separate property and are not affected by this Agreement. Sponsor shall have exclusive ownership of any inventions or discoveries arising in whole or in part from Confidential Information or arising as a result of the Study. The Investigator and Institution will, at Sponsor's expense, execute any documents and give any testimony necessary for Sponsor to obtain patents in any country or to otherwise protect Sponsor's interests in such inventions or discoveries.

_____ **Payments**

Direction of Payment

Our required provision is:

Checks shall be made payable to 'Maine Medical Center' and mailed to Maine Medical Center c/o Jeffrey Winchenbach, Director, Financial Services, 22 Bramhall Street, Portland, ME 04102-3175; Tax ID #01-0238552. All payments shall be accompanied by a cover statement that refers to the name of the study and principal investigator and refers to what the payment covers – i.e., quarterly scheduled payment, payment per Study participant, completion of edited case reports, etc.

Prorated Payment

Required provision:

In the event of termination, the sums payable by Sponsor to Institution hereunder shall be prorated to account for actual work performed to the date of termination and Institution shall be reimbursed the cost of any non-cancellable expenses incurred by Institution/Investigator in connection with this Study.

Screen Failures

Sponsor shall reimburse Institution for Study subjects that are ineligible for enrollment after being pre-screened and signing an informed consent form but only up to eight (8) such screen failures (at a maximum ratio of 1 screen failure per two Subjects actually enrolled). Sponsor shall reimburse Institution for such screen failures (actual personnel costs and screening procedures identified in Table __) up to a maximum of $____ for each such screen failure, following Sponsor's receipt and approval of a detailed invoice.

Upfront Costs

Sponsor agrees to reimburse Institution for a one-time administrative study start up fee for time spent on regulatory document preparation and submission, and other activities required for study activation following Sponsor's review and approval of a detailed invoice. All start up funds are non-refundable.

_____ **Publication Rights**

Preferred provision:

Institution/Investigator shall have the right to publish study data and results provided that Institution/ Investigator submits a copy of any proposed publication or presentation to Sponsor for review and comment at least sixty (60) days prior to such planned presentation or submission for publication. If Sponsor does not provide comments to Institution/Investigator within thirty (30) days of receipt of such proposed publications, abstracts or oral presentations, then Sponsor shall have waived its right to comment on the content or proposed presentation, abstract or publication.

Sponsor agrees to ensure that the Study is registered on a publicly accessible internet site in accordance with all laws and regulations required for clinical trial registration and under the guidelines of the International Committee of Medical Journal Editors ("ICMJE").

____ **Record Retention**

Our preferred provision is that Institution is not required to retain records for more than seven years past the completion of the Study.

Should Sponsor request notification prior to destruction at the end of set period of time, our preferred position is:

At the end of such period, should Sponsor want records to be preserved, Sponsor shall send Institution written notice at least thirty (30) days prior to the expiration of the retention period requesting records not to be destroyed. Sponsor's request for extended record retention shall include the duration of the requested extension period. Institution shall either accept the extended record retention request or coordinate the transfer of the materials to Sponsor. Failure of Sponsor to send written notice to Institution requesting a record retention period extension shall be evidence of Sponsor's acquiescence in the destruction of such material.

_____ **Regulatory Inspections/Audits**

If any governmental or regulatory authority (a) contacts the Principal Investigator with respect to the Study, (b) conducts, or gives notice of its intent to conduct, an inspection that could reasonably be expected to impact any data or clinical activity under the Study or (c) takes, or gives notice of its intent to take, any other regulatory action with respect to any activity of the Principal Investigator that could reasonably be expected to impact any data or clinical activity under the Study, then the Principal Investigator shall promptly notify Sponsor of such contact or notice. Except as limited by such authorities rules and regulations, Sponsor shall be given the right to be present at and to participate in any such inspection or regulatory action with respect to the Study. The Principal Investigator shall provide Sponsor with copies of all pertinent information and documentation issued by any governmental or regulatory authority directly related to the Study and any proposed response. Sponsor shall be given the opportunity to review in advance any responses which pertain to the Study, and to provide comment which Principal Investigator will consider in good faith. However, Sponsor acknowledges that Sponsor may not direct the manner in which the Principal Investigator fulfills his/her obligations to permit inspection by governmental entities. It shall not be a breach of this Agreement for Principal Investigator to comply with the demands and requests of any governmental entity, however, the Principal Investigator shall have an obligation to contact Sponsor first, if permitted by law, before complying with any such demand or request. No such response shall contain any false or misleading information with respect to the Study, the Study Drug or Sponsor.

_____ **Stark Law**

In order to comply with federal Stark Law requirements, the Institution cannot make payments to non-employed physicians or physician private practices for services related to a clinical study until a contract is in place. The contract must detail the scope of work (services) that the physician investigator will provide relative to the study. Therefore, a Stark Law contract must be in place prior to a physician investigator providing bill-able services on a clinical study. If the physician investigator does provide services and his practice invoices MMC, MMC will be unable to pay the practice for the services since an appropriate contract was not in place. If a fully executed clinical study agreement is in place between MMC and the sponsor, patients, however, can be enrolled into the study (as long as other appropriate approvals are in place [IRB]).

_____ **Subject Injury**

Preferred provision:

Any adverse event or injury that is attributable to the Study participant's underlying disease or an acknowledged risk or complication of a clinically indicated procedure shall be the responsibility of the Study participant, who shall be responsible for the basic costs of care related to the illness, which costs shall be billed to the Study participant's insurance coverage, if any.

The Sponsor, however, shall pay for all reasonable and necessary medical expenses incurred by a Study participant as a direct result of an adverse event specifically attributable to the investigational component of the treatment or device when used as specified by the protocol, provided the adverse event is in no way attributable to the negligence or misconduct of any employee of the Institution. No other compensation of any type will be provided by the Sponsor to the Study participants.

If no subject injury provision, confirm in writing that this is observational study.

If the Sponsor asks for us to first seek insurance coverage from the study subject's third party payor, our position is: Our position is that it is not appropriate to ask the subject's insurance carrier to defray such costs when they are attributable to participation in the study and not to the underlying disease or condition being treated. The compromise we offer is one that we have accepted on some occasions - that we will state that we will not look for the sponsor to cover such costs to the extent they are covered by third party insurance but that we are under no obligation to seek third party coverage. That clause assures the sponsor that there will be no double billing, but we avoid the hassle and delay of seeking third party coverage and only getting reimbursement from the sponsor after such coverage is denied.

Note: Under Medicare and Medicaid, MMC cannot bill patients' insurance company for research-related procedures or injury if directly related to the Study drug/device.

Any deviation from the above standard subject injury language must be reported to Sue Libby and/or Linda Reinholdtsen in the Office of Research Administration, MMCRI, Scarborough Campus, tel: 207- 885-8184; fax: 207- 885-8141; e-mail: libbys@mmc.org*) to ensure that any revision(s) are also included in the informed consent document that is approved by the IRB.*

_____ **Termination/Reciprocal**

Preferred provision:

Institution/Investigator shall have the right to terminate this Agreement at any time without cause upon thirty (30) days prior written notice; and

Institution/Investigator shall have the right to terminate this Agreement at any time upon thirty (30) days' prior written notice to Sponsor if Sponsor breaches any material term of this Agreement and fails to cure said breach within the thirty (30) days of receipt of notice of such breach; and

Institution/Investigator may terminate this Agreement at any time if, in the opinion of Institution and/or Investigator, such termination is required to protect Study participant's safety or is in the Study participant's best interest.

Institution/Investigator may terminate this Agreement at any time if cumulative protocol changes, since this Agreement was originally signed, increase the Institution's cost or risk of conducting the Study by more than 2% and the parties are unable to agree on a revised budget within thirty (30) days.

_____ **Who are the parties and who is signing**

If the Agreement is to be signed only by a CRO, MMC requires a **separate** Letter of Indemnification on Sponsor letterhead and signed by the Sponsor.

____ **PI Signature line**

Required provision:

Principal Investigator hereby agrees to accept responsibility for the conduct of the Study, acknowledges having reviewed this Agreement, and agrees to be bound by the terms and conditions stated herein.

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